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February 14, 2005

HAND DELIVERED

Jonathan L. Trout, Secretary-Treasurer
Louisville Metro Air Pollution Control Board
850 Barret Avenue
Louisville, Kentucky 40204-1745

Re: Proposed STAR Program – Formal Comments

Dear Mr. Trout:

LG&E Energy (“LG&E”) is a leader in the implementation of air pollution control technology and understands the importance of air quality, not only as it relates to the public’s health, but also as it relates to the economic development of Louisville Metro and the vitality of the community. For that reason, LG&E supports the development of a scientifically sound air toxics program that fully addresses the concerns of this community, including industry.

As an industry leader and a member of the Louisville Metro community, LG&E is committed to environmental stewardship and decision making. LG&E has undertaken a detailed review of the proposed STAR Program, the Louisville Metro Air Pollution Control District’s (District) response to comments made during the informal comment period, and the Preliminary Regulatory Impact Assessment (“the PRIA”) prepared by the District. We have spent many hours trying to understand how the proposed STAR Program will apply to our operations in Louisville Metro and what will be necessary to achieve compliance.

Due to the complexity of the proposed STAR program and the potential impact to our ratepayers, LG&E sought independent peer-review from Signature Science LLC, a nationally recognized consulting company with expertise in an array of technical services including the field of toxicology. This peer-review demonstrates that the proposed STAR program is excessively stringent and is not based upon sound science.

The detailed final comments provided with this letter were prepared in an effort to enhance community-wide communications and provide additional technical justification in support of a “true” stakeholder process. Such a process should include diverse membership in order to assure that we, as local citizens, have the best possible air to

breathe while preserving a healthy and vital economy. The talent exists within our community to find and achieve that balance.

In conclusion, a more refined risk assessment process is needed to make determinations of health risk to our community -- where we live, work and play. A STAR program that is in the community's best interest and will not force needless expenditures, "false positives" or erroneous conclusions, is deserved by all.

LG&E has highlighted below a few significant unreasonable and unsupported areas of concern, with the proposed regulations:

- The decision to expand the STAR Program to regulate more chemicals than those 18 identified as constituents of concern in the West Louisville Air Toxics Study (WLATS) and those that are not identified by U.S. EPA as Hazardous Air Pollutants ("HAPs");
 - For example, the arbitrary selection and addition of sulfuric acid to the Category 2 TAC group could cause an undue economic burden to this community and our ratepayers. On a national level, U.S. EPA has not developed toxicity factors for sulfuric acid. At a local level, the District has not demonstrated any adverse health impact to the area. In addition to not being identified as a Category 1 TAC as part of the WLATS, sulfuric acid is not listed as an Urban Air Toxic or a hazardous air pollutant by U.S. EPA.
 - Based on our current understanding of the proposed STAR Program, a cost range of \$20 million to \$700 million dollars could be incurred to control sulfuric acid on units that already protect the environment through existing pollution control equipment and continue to be heavily regulated by federal, state and local regulation.
- Concern with the scope of the risk-based program developed by the District, including, the methodologies used to evaluate risk under the proposed STAR Program and the maximum ambient air concentrations of toxic air emissions, the appropriateness of selecting methodologies from other state air toxic programs in part, but not in total, and the District's basis for differing from federal law;

Implementation of these regulations will not only put an undue economic burden on the regulated community without achieving a comparable increase in the protection of health and welfare, it will also unnecessarily consume limited agency resources and potentially result in agency-driven bottlenecking that will dramatically slow the permitting process.

LG&E respectfully submits the following formal comments, which outline our concerns on the proposed STAR Program, for consideration by the Louisville Metro Air Pollution Control Board ("the Board"). LG&E is disappointed that the District developed the

proposed STAR Program without stakeholder input and involvement, although we appreciate the District's participation in the roundtable discussions held at the request of the Strategy Committee of the Board and in discussions with LG&E.

LG&E generally endorses the comments submitted by Greater Louisville Inc. ("GLI") and the Associated Industries of Kentucky ("AIK"), though neither those comments nor the comments of any stakeholder can be viewed as an adequate substitute for a fully developed and meaningful stakeholder process -- a critical step in promoting mutual trust and confidence between administrative agencies and the public they serve by ensuring that the public has access to timely and accurate information upon which to evaluate risks and consider alternatives.¹

We are confident that the Board will carefully consider the comments submitted during the formal comment period and revise the proposed STAR Program as necessary and appropriate prior to its adoption. If you have any questions, please contact me at (502) 629-2940. LG&E looks forward to your response.

Respectfully submitted,



Sharon L. Dodson
Director, Environmental Affairs
LG&E Energy LLC

Hon. Jerry Abramson
Mr. Bruce Traughber
APCD Board Members
Metro Council Members

¹ See *Public Involvement Policy of the U.S. Environmental Protection Agency*, May 2003.

Formal Comments

Strategic Toxic Air Reduction Program (STAR)

LG&E Energy

February 14, 2005

I. The Scope of the Risk Based Program

The risk based program established in the proposed STAR Program is found in Part 5 of the regulations. The comments of Lucy Frasier, Ph.D., DABT, a Senior Toxicologist with Signature Science LLC,¹ on the proposed regulations are as follows:

A. Signature Science LLC's Review and Critique of the Proposed STAR Program

1. General Comments

A more refined risk assessment process is needed to make determinations of "true" risk. Screening risk assessments, with rare exception, estimate risks that are excessive, which can mislead the regulatory process, unnecessarily raise public concern, and possibly miss identification of the most important risks. The use of implausible and unrealistic methods, models, data, and assumptions, particularly when better methods and data are easily obtained, is clearly inappropriate and will very likely lead to erroneous conclusions. While further regulation of any source that is found to *clearly and unambiguously* exceed acceptable risk levels is supported, the District should be sensitive to the potentially profound economic impacts of further regulating sources that have already expended tremendous resources in meeting MACT, NAAQS, TLVs and other federally-mandated air quality standards. It is not in the community's best economic interest to force needless expenditures when estimated risks associated with potential emissions are not high relative to typical background risk encountered by the general population on a day-to-day basis.

Experience has shown that the use of upper bound generic risk-based approaches usually provides a poor basis for regulatory actions as they tend to fail at screening any sources out of the process, producing instead many "false positives". (Testimony of Elizabeth L. Anderson before the senate Environment and Public Works Committee, October, 2000;

¹ A copy of Dr. Frasier's resume is attached as Appendix 1.

<http://epw.senate.gov/107thand1003.htm>). Widespread non-compliance is likely to be the result of implementing the draft regulations in their current state. Implementation of these regulations will not only put an undue economic burden on the regulated community without achieving a comparable increase in the protection of health and welfare, it will also unnecessarily consume limited agency resources and potentially result in agency-driven bottle necking that will dramatically slow the permitting process. Approaches that slow the permitting process have the potential to allow process emissions to go “unchecked” for years while the permit provisions are being established and should be avoided.

2. Tiered Risk-Based Decision Making Approach

As opposed to using BACs as “bright lines” that are not to be exceeded, a three-tiered risk-based process should be proposed under the draft regulations. Recommended tiers in the process include: 1) an initial, conservative screening assessment of potential risk to conserve resources; 2) a second more refined assessment if risks from the initial screening are of potential concern; and 3) if risks from the refined assessment are of potential concern, further refinement using more site-specific and industry-specific information to develop a more accurate assessment of potential risk posed by emissions.

Tiered approaches for evaluating health and welfare effects are the norm, with the first tier consisting of specific decision points and exit criteria and the later tiers representing progressively more complex levels of review and each level requiring more detailed information. (Navy policies for Conducting Human Health Risk Assessments [See <http://5yrplan.nfesc.navy.mil/policies/policies.htm>]; CAA mandated OAQPS Residual Risk Program [See <http://www.epa.gov/ttn/atw/urban/appx1011.pdf>]; HEM Exposure Model (See http://www.epa.gov/ttn/fera/human_hem.html; Ohio EPA [See <http://www.iet.msu.edu/regs/state/Ohio/ohundertanks.htm>]; Texas Risk Reduction Program [See 30 TAC 350, [http://info.sos.state.tx.us/pls/pub/readtac\\$ext.ViewTAC?tac_view=4&ti=30&pt=1&ch=350](http://info.sos.state.tx.us/pls/pub/readtac$ext.ViewTAC?tac_view=4&ti=30&pt=1&ch=350)]) The following represents a tiered approach that would be protective of human health and welfare but allow flexibility into the STAR program by providing a means by which a source could more accurately demonstrate compliance with the proposed STAR Program: 1) If the maximum ground level concentration (GLC_{max}) is less than the benchmark, then the GLC is acceptable and the facility would be in compliance; 2) For constituents whose GLC_{max} exceed the benchmark, if the GLC_{max} occurs on industrial property and does not exceed the benchmark by more than two times, and the GLC at the nearest non-industrial receptor does not exceed the benchmark, then the GLC is

acceptable and the facility would be in compliance; 3) If the GLC does not meet these criteria, then a Tier III evaluation commences. A Tier III evaluation incorporates additional case-specific factors that have bearing on the exposure scenario. The following would be considered under such a review:

- Surrounding land use (can non-industrial receptors be exposed?)
- Magnitude of the GLC exceedance
- Frequency of exceedance (how many hours/yr does GLC exceed benchmark?)
- Background concentrations of the constituent
- Type of toxic effect caused by constituent (if acute effects are of concern, then short-term exceedances would be of concern, if it is primarily a chronic toxicant, then long-term exceedances would be of concern)
- Margin of safety between the BAC and known effects levels – if there is a big difference between the BAC and the published No Observed Adverse Effect Level (NOAEL) or levels at which humans have exhibited toxicity, then there may be flexibility in approving GLCs that exceed the BAC (this determination requires input from an experienced toxicologist, epidemiologist, or another person with appropriate background)
- Degree of confidence in the toxicity database – for constituents with many reliable toxicity and/or epidemiological studies, there is a higher degree of confidence in what we have identified as harmful levels, and similarly, levels that will not cause adverse effects. For other constituents, adequate information does not exist. For these constituents, exceedances would be viewed more stringently due to uncertainties about levels at which adverse effects may occur.

These factors would need to be reviewed and summarized by a qualified toxicologist, epidemiologist, or someone with a relevant medical background who could develop a final opinion about the likelihood that emissions would increase the risk of adverse health or welfare effects. If the potential for public exposure is found to be extremely low, the air modeling predicts low frequency of high concentrations, the predicted concentrations are exaggerated and the overestimation can be quantified, then exceedances of two, three, or even 10 times the BAC may be acceptable from a health protection perspective. This type of approach is consistent with the approach utilized by other state agencies, such as the Texas Commission on Environmental Quality (TCEQ). (Modeling and

Effects Review Applicability: How to Determine the Scope of Modeling and Effects Review for Air Permits [See http://www.tnrcc.state.tx.us/permitting/airperm/nsr_permits/files/mera.pdf].

3. Risk Range Goals

The establishment of target cancer risk values at 1×10^{-6} and 3.8×10^{-6} and hazard quotients at a fraction of one represents a regression in public policy and ignores recommendations of the federal government to seek greater consistency in approaches to assessing public health risks of exposure to environmental contaminants. Target risk and hazard levels that have most often been used in the past for making risk management decisions are 1×10^{-4} and 1, respectively. Cases can be cited in which cancer risks that are even higher than 1×10^{-4} have been used/approved, depending on size of the population exposed and/or other mitigating factors. A target hazard index of 1 has traditionally been the norm, but values greater than one (1) are becoming more common. For example, the Texas Commission on Environmental Quality (TCEQ) uses a cumulative target hazard index of 10 under its risk-based corrective action program (i.e., the Texas Risk Reduction Program at <http://www.tnrcc.state.tx.us/permitting/remed/techsupp/guidance.htm>). Given the multitude of conservative assumptions incorporated into the methods prescribed under the draft regulations, target risk and hazard levels higher than those proposed could be easily justified and are addressed further below.

The District should take a similar approach as that taken under the residual risk requirements (section 112(f)) of the 1990 Amendments to the Clean Air Act by distinguishing between the “aspirational goal” of 1×10^{-6} and limiting potential risks to 1×10^{-4} by setting this level as a “trigger” for action. Determining an acceptable risk goal is essential for developing BACs to limit excess cancer risk in exposed populations. The acceptable risk goal selected should be reasonable, taking into account the rate of cancer mortality in the general population.

Protective standards for human health are typically set at concentrations that result in the total risk to a continuously exposed individual falling within the “target range” from 1×10^{-4} (probability of one additional cancer case in ten thousand people) to 1×10^{-6} (probability of one additional cancer case in one million people). These additional cancer cases should be considered against the probability that between one-third and one-half of all Americans will develop a cancer over the course of their lifetimes. (Cancer Facts & Figures 2005 [See

<http://www.cancer.org/downloads/STT/CAFF2005f4PWSecured.pdf>).

For instance, if the probability of developing cancer in the general population is typically 0.33, then exposure to a carcinogen at acceptable risk levels of 1×10^{-4} and 1×10^{-6} results in a probability of getting cancer of 0.3301 and 0.330001, respectively. This is an increase in cancer of only 0.000001 when goals are set at 1×10^{-6} . The difference in cancer risk attributable to exposure corresponding to these acceptable risk levels is very small compared with the probability of developing cancer overall. Furthermore, despite the fact that a 1 in a million (i.e., 1×10^{-6}) cancer risk is routinely used as a target in risk evaluations, many other activities that are routinely and voluntarily engaged in by the general public increase the chance of death by 1 in a million (yearly) include:

1. Eating 100 charbroiled steaks (cancer from benzo(a)pyrene exposure)
2. Drinking 30 12oz cans of diet soda (cancer from saccharin)
3. Living two months with a cigarette smoker (cancer, heart disease)
4. One chest x-ray taken at a good hospital (cancer from radiation)
5. Flying 6,000 miles by jet (cancer from cosmic radiation)

Examples taken from: Readings in Risk, 1993. Glickman and Gough Eds.

Under the residual risk requirements under section 112(f) of the 1990 Amendments to the Clean Air Act U.S. EPA, published risk decision-making policy “goals” of: 1) protecting the greatest number of persons possible to an individual lifetime cancer risk level no higher than approximately one in one million (1×10^{-6}); and 2) “limiting” cancer risk to no higher than approximately one in ten thousand (1×10^{-4}) for a person living near a source (Residual Risk Report to Congress [EPA, 1999] at <http://permanent.access.gpo.gov/websites/epagov/www.epa.gov/ttn/oarpg/t3/reports/risk/rep.pdf#search='residual%20risk%20program'>). U.S. EPA further stated that a maximum individual risk (MIR) of one in ten thousand should ordinarily be the upper end of the range of acceptability, or “bright line” (Residual Risk Report to Congress [U.S. EPA, 1999]). As risks increase above this benchmark, U.S. EPA stated that they become presumptively less acceptable under section 112, and would be weighed with the other health risk measures and information in making an overall judgment on acceptability. This risk policy has largely been accepted and it was codified in the 1990 Amendments in section 112(f)(2)(B), U.S. EPA’s Residual Risk Program.

The District should consider establishing a hazard quotient that is greater than 1 (one). Throughout the response to comments, the District defends its use of a hazard quotient of one (1) stating that it represents the concentration above which adverse health effects could be expected. First, the District's lack of precision in responding to comments using incorrect definitions/terminology creates additional confusion and misunderstanding. A hazard quotient is not a concentration. It is a unit less value representing the ratio between the air concentration and the RfC. (Risk Assessment Guidance for Superfund, Volume 1: Human Health Evaluation Manual, Part A [U.S. EPA, 1989]). The RfC influences the hazard quotient since it is the divisor in the ratio, but it is not technically correct to use the two synonymously.

Presumably the District intended to state that the RfC is the concentration above which adverse health effects could be expected. However, according to IRIS, an RfC (which serves as the divisor in the hazard quotient) is "An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." (Risk Assessment Guidance for Superfund, Volume 1: Human Health Evaluation Manual, Part A [U.S. EPA, 1989]). Stating that the RfC is the concentration above which health effects could be expected is not synonymous with U.S. EPA's definition of "...a concentration that is likely to be without an appreciable risk." The first problem with assuming that any concentration above the RfC could result in adverse health effects is that it treats the RfC as a "bright line", which they are not intended to be. The use of order-of-magnitude uncertainty factors for RfCs and the definition of RfC as having "uncertainty, spanning perhaps an order of magnitude" are clear indications of the general lack of precision in the estimates. While the definition states that the uncertainty spans perhaps an order of magnitude, (IRIS Glossary at <http://www.epa.gov.iris/gloss8.htm>), those familiar with their derivation understand that the uncertainty likely spans several orders of magnitude. (Evolution of Science Based Uncertainty Factors in Non-Cancer Risk Assessment by Michael L. Dourson, Susan P. Felter, and Denise Robinson, Regulatory Toxicology and Pharmacology, Vol. 24, 1996 [See <http://www.tera.org/pubs/paper.htm>]). For example, while some of the BAC values proposed in the rule are based on human data, most are based on controlled studies conducted on laboratory animals. When animals are used to develop these toxicity values, uncertainty factors ranging from 100 to 1000 are used to account for differences between toxicity in laboratory animals and humans, as well as to account for differences between members of the exposed population. The greater the overall magnitude of the uncertainty factor (i.e., the more individual uncertainty factors that were combined to get the total uncertainty factor),

the more conservatism is included (Residual Risk Report to Congress [EPA, 1999]). In applying these uncertainty factors, humans are always assumed to be more sensitive to the toxic effects of chemicals than are animals, which is known not to be true for many chemicals. According to the Residual Risk Report to Congress (EPA, 1999), "It should be noted that exposures above an RfD or RfC do not necessarily imply unacceptable risk or that adverse health effects are expected. Because of the inherent conservatism of the RfC/RfD methodology, the significance of exceedances must be evaluated on a case-by-case basis, considering such factors as the confidence level of the assessment, the size of uncertainty factors used, the slope of the dose-response curve, the magnitude of the exceedance, and the number or types of people exposed at various levels above the RfD or RfC. Treating the RfC (or the hazard quotient indirectly) as "line in the sand" that is not to be crossed, particularly when the compliance point and compliance concentrations are determined using highly conservative procedures that overestimate actual concentrations, is likely to result in wide-spread non-compliance.

Target hazard indices and quotients of one (1) have traditionally been the norm, but values greater than one are becoming more common. For example, the Texas Commission on Environmental Quality (TCEQ) uses a cumulative target hazard index of 10 under its risk-based corrective action program 30 TAC 350 Hazard indices reported under the Residual Risk Program are reported over a range of hazards from < 0.2 to 10 as well.

BACs Toxicity benchmarks (i.e., BACs) proposed under the draft regulations should serve as guidelines, not standards. Screening air models intended to provide conservative estimates of maximum air concentrations are used in conjunction with conservative BAC values. The combination of overestimates of actual air concentrations with highly conservative health benchmarks will almost certainly grossly overestimate actual risk posed to individuals living near a source and result in wide-spread non-compliance.

BACs should be used as "screening" tools only, to separate constituent concentrations that would not be expected to cause adverse health and welfare effects from those requiring a more detailed review. Health-based BACs are not threshold values for adverse effects. In fact, they are set at levels far below those which have been shown to cause adverse health effects in humans or laboratory animals. This margin of safety is included to account for uncertainties or differences in available data. Constituents tend to cause a spectrum of possible effects based on increasing exposure level (for example, odor at low concentration, mucous membrane irritation at intermediate concentration, and organ damage at high concentration). BACs are set to protect against the effect occurring at the lowest adverse

effect concentration. If a predicted GLC is below a BAC, then no adverse health effects are expected. However, if a GLC exceeds a BAC, that exceedance is not necessarily an indication that an adverse effect will occur, but rather that further evaluation is warranted. (TCEQ, 2001 [See http://www.tnrcc.state.tx.us/permitting/airperm.nsr_permits/files/mera.pdf]). This approach is consistent with essentially every other Air Toxics program in the country. [See, for example TCEQ, 2001].

5. Listing/Delisting Procedure for TACs

The District should consider establishing listing and delisting criteria similar to those found in other laws, regulations, exposure guidelines, and policy statements. Establishment of listing criteria would obviate the need to derive default toxicity benchmarks, such as the BACnc of 0.04 and BACc of 0.0004 $\mu\text{g}/\text{m}^3$, which lack a sound scientific basis (see comment below). For hazardous air pollutants (HAPs), listing/delisting criteria generally consist of a definition of HAPs, and the procedures for establishing that a pollutant is or is not consistent with that definition. HAPs definitions generally exclude pollutants as regulated under other laws or regulations (e.g., "criteria" pollutants regulated by EPA, or airborne contaminants in workplaces regulated by the OSHA), and pollutants that are not emitted during routine operations (e.g., accidental leaks and constituents such as carbon tetrachloride which are no longer used in industrial processes). The definitions also differentiate HAPs from other ambient air pollutants based on their known or potential effects on human health or the environment. HAPs are usually chemicals that may cause "adverse" effects on human health and the environment. This portion of the definition would exclude the need to develop surrogate toxicity benchmarks for those compounds for which toxicity data are lacking. Also, definitions may distinguish HAPs from other pollutants by specifying the types of effects to be avoided and the severity of these effects. Some states have established numerical toxicity rating systems to decide which pollutants to regulate. Often the initial list of HAPs consists of pollutants recognized as human toxicants by an organization that has performed a detailed evaluation of many contaminant such as EPA.

6. Regulation 5.20 Methodology for Determining Benchmark Ambient Concentration of a Toxic Air Contaminant

a. Section 3 Chronic Cancer Risk Benchmark Determination Methodology

3.1 URE = Unit Risk Estimate – The definition given in the regulations differs from that provided in U.S. EPA's

Integrated Risk Information System (IRIS) and should be corrected. The definition provided in IRIS is:

“The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 $\mu\text{g/L}$ in water, or 1 $\mu\text{g/m}^3$ in air.”

The definition provided in the regulations is:

“Additional lifetime cancer risk occurring in a population in which all individuals are exposed continuously for life (70 years) to a concentration of 1 $\mu\text{g/m}^3$ of the chemical in the air they breathe, in units of $(\mu\text{g/m}^3)^{-1}$.”

This definition appears to be a misinterpretation of the IRIS definition and is misleading because it suggests that a 70-year exposure duration is inherent to U.S. EPA’s standard definition of a Unit Risk Factor or Estimate. It is correct that U.S. EPA’s Unit Risk Factor corresponds to a “lifetime” risk and the default “lifetime” for the U.S. population is considered to be 70 years. However, there is nothing in the IRIS definition indicating that individuals are exposed continuously for life (70 years). In carcinogen risk assessment, the dose is averaged across a lifetime (i.e., over 70 years) but exposure does not necessarily occur over the entire lifetime. Carcinogen risk assessments more often than not assume an exposure duration that is considerably less than a lifetime. This is because national statistics indicate that the 90th percentile time that individuals live in a single residence is 33 years, with an average time in a single residence of 9 years (U.S. EPA, 1997). The median occupational tenure of the working population is about 7 years. Therefore, very few individuals are likely to be exposed over a 70 year time period and a 70-year exposure duration should not automatically be assumed simply because a Unit Risk factor is being used to quantify risk.

3.3.2 UREs developed by the California Office of Environmental Hazard Assessment (OEHHA) should not be automatically adopted without evaluating their bases. For example, a BACc of 0.08 $\mu\text{g/m}^3$ is listed for lead in the BAC table and references a California EPA URE. However, IRIS states that “Quantifying lead’s cancer risk involves many uncertainties, some of which may be unique to lead. Age, health, nutritional state, body burden, and exposure duration influence the absorption, release, and excretion

of lead. In addition, current knowledge of lead pharmacokinetics indicates that an estimate derived by standard procedures would not truly describe the potential risk.” For these reasons, EPA’s Carcinogen Assessment Group has recommended that a numerical estimate not be used. Despite this recommendation, California EPA used the standard linearized multistage model to develop a URE for lead. Even California EPA’s documentation (http://www.oehha.ca.gov/air/cancer_guide/TSD2.html#download) for the lead URE states “Epidemiological studies and case reports of people occupationally exposed to lead provide some evidence of carcinogenicity but are not convincing due to lack of controlling for confounders such as smoking and to the simultaneous exposure of some workers to known human carcinogens including arsenic and cadmium. These studies have been reviewed by several agencies (IARC, 1980; U.S. EPA, 1986; 1989a; 1989b; ATSDR, 1990).”

The California documentation for the lead URE also states that “No long-term studies in animals to investigate carcinogenicity due to lead inhalation have been conducted.” Because there are no long-term animal inhalation studies for lead, information from a series of different studies had to be used by California EPA to develop the lead URE. First, it was assumed that the percentage of lead absorbed by inhalation is similar for rats and humans. No data were cited to support this assumption and it is now generally recognized that it is necessary to make dosimetric adjustments to account for the species-specific relationships of exposure concentrations to deposited/delivered doses (Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry [EPA, 1994]. Next, it was assumed that an average adult human has a body weight of 70 kg and an average air intake of 20 m³ per day. These are standard assumptions that were used extensively in the past before the many of the underlying assumptions associated route-to-route extrapolation were fully appreciated. However, based on these standard assumptions, an oral intake of 1 mg/kg/day lead is equivalent to an inhalation exposure of 3,500 µg/m³/day. Using the latter units and the standard linearized multistage model, the 95% UCL for q1 equals $2.4 \times 10^{-6} (\mu\text{g}/\text{m}^3)^{-1}$, which assumes equivalent absorption by the 2 routes. Finally, it was assumed that lead is absorbed more efficiently by inhalation than ingestion (5 times more efficiently based on available human data). If there is approximately 5 times higher absorption by the respiratory tract as compared to the gastrointestinal tract (Owen, 1990), the inhalation risk can be multiplied by 5 and the corrected inhalation unit risk is 1.2×10^{-5}

($\mu\text{g}/\text{m}^3$)⁻¹. As illustrated, many assumptions were made to derive the lead URE and it is difficult to accept the California lead URE as scientifically supportable. It is also notable that almost no other agencies treat lead as a carcinogen.

This is but one example of why broad adoption of air quality health benchmarks developed by other state agencies without evaluating their bases is ill advised. Additional examples may be provided upon request.

EPA published a set of cancer risk assessment guidelines (Guidelines for Carcinogen Risk Assessment [EPA, 2003]) and has been working for years to revise those cancer guidelines to reflect advances in scientific understanding as well as experience in using them. The guidelines and revisions have been subject to extensive public comment and scientific peer review, including three reviews by EPA's Science Advisory Board. It is difficult to believe that staff of the California EPA is better suited to make determinations of cancer potency than U.S. EPA.

3.3.2

UREs developed by the Michigan Department of Environmental Quality should not be automatically adopted without evaluating their bases. The Michigan Department of Environmental Quality Air Toxic Rules does not establish listing/delisting criteria for air toxics. The rules define toxic air contaminant as "...any air contaminant for which there is no national ambient air quality standard and which is or may become harmful to public health or the environment when present in the outdoor atmosphere in sufficient quantities and duration." (http://www.michigan.gov/deq/0,1607,7-135-3310_4105-11749--,00.html). This "catch all" definition of air toxics allows the agency to establish health criteria on the basis of presumed health effects. In a number of instances, these health effects are unsubstantiated by Federal agencies with the expertise to develop such criteria. For that reason, Michigan ITSL and IRSLS provide a poor basis for regulatory action.

The bases of the Michigan ITSLs and IRSLS are not transparent. Documentation of their derivation is not provided on the Agency's website and the source of the values is not referenced well enough to allow an interested party to discern the basis for benchmarks developed by the agency. For example, Michigan IRSL of 0.3 mg/m^3 is listed for naphthalene, with EPA 1998 as the reference. The source of the naphthalene IRSL would appear to be the Toxicological Profile available for naphthalene on EPA's website

(<http://www.epa.gov/iris/toxreviews/0436-tr.pdf>), although this cannot be determined for certain because full references are not provided for the Michigan IRSLS. However, according to the Toxicological Profile available for naphthalene on U.S. EPA's website, "data for humans are inadequate to evaluate a plausible association with cancer. Observations of predominantly benign respiratory tumors in mice exposed to naphthalene by inhalation for 2 years (NTP, 1992a) or to 1-methylnaphthalene in the diet for 81 weeks (Murata et al., 1993) provide suggestive evidence for the carcinogenicity of naphthalene, **but the evidence is insufficient to assess the carcinogenic potential of naphthalene in humans.** No quantitative cancer dose-response assessments (dose conversion, extrapolation methods, oral slope factor, or inhalation unit risk) for naphthalene are presented at this time **due to the weakness of the evidence that naphthalene may be carcinogenic in humans.**"

U.S. EPA published a set of cancer risk assessment guidelines (Guidelines for Carcinogen Risk Assessment [U.S. EPA, 2003]) and has been working for years to revise those cancer guidelines to reflect advances in scientific understanding as well as experience in using them. The guidelines and revisions have been subject to extensive public comment and scientific peer review, including three reviews by U.S. EPA's Science Advisory Board. It is difficult to believe that staff of the Michigan Department of Environmental Quality is better suited to make determinations of cancer potency than U.S. EPA, particularly given that detailed procedures for developing these alternative cancer potency factors are not provided by the agency.

This is another example of why broad adoption of air quality health benchmarks developed by other state agencies without evaluating their bases is ill advised. Additional examples may be provided upon request.

- 3.3.3 The District should not establish a default BACc value for compounds that lack toxicity values developed by other reputable agencies.** The basis for the recommended default BACc of $0.0004 \mu\text{g}/\text{m}^3$ is unclear in the regulation and the rationale provided in the District's response to comments is not persuasive. Risk-based regulatory programs that set *de minimis* levels without rational consideration of health and environmental impact of the pollutant lose all credibility with the regulated community and ultimately the citizens they are established to protect.

The District's responses to comments provide a description of two approaches taken to come up with the $0.0004 \mu\text{g}/\text{m}^3$ default BACc. The first approach (the 90th percentile BACc for constituents listed) is not a reasonable approach because the possible distribution of BACc values is governed completely by those compounds listed as TACs in the District's draft regulations. The list of TACs includes a total of 37 constituents, only 20 of which are considered to be carcinogenic under this set of regulations. Toxicity criteria for close to 600 constituents are listed on the IRIS website. If a distributional approach is to be taken, then the District should consider the entire distribution of all possible values for cancer benchmarks developed to date rather than the fraction of the total distribution represented by the Category 1 and 2 TACs.

The second approach is equally if not more illogical because the mechanism by which a particular compound causes cancer and non-cancer health effects may be completely different. In addition, completely different target organ systems may be involved in cancer and non-cancer responses. For these reasons, a quantifiable relationship between cancer and non-cancer health effects for the same compound cannot be reliably established.

The principal issue is whether this *de minimis* level of $0.0004 \mu\text{g}/\text{m}^3$ protects public health. Despite the fact that the District states that it considers this default value to be one that will provide a reasonable level of protection, it is not possible to determine if this default level provides an adequate margin of safety for human health under all circumstances for all compounds lacking a URE or if it is excessively overprotective. There is no demonstrable benefit associated with regulating unknowns using default toxicity benchmarks and, therefore, promulgation of such default BACs should be seriously reconsidered.

- 3.3.4 Calculation of toxicity benchmarks for compounds that lack UREs established by reputable agencies such as U.S. EPA should not be required by the regulation.** In developing toxicity benchmarks, a risk assessor must be able to first fully understand the toxicity information that ultimately forms the basis of the benchmark (in this case a BAC) and then must be able to synthesize it, put it into context and use exposure and effects data to arrive at a quantitative estimate of toxicity. This requires a thorough understanding to toxicology, pharmacokinetics, accepted toxicology testing protocols, and standard paradigms for incorporating toxicity information into regulatory programs. Very

few members of the regulated community will have such individuals on staff and industry would, therefore, likely need to hire consultants to develop these BACs. Furthermore, it is doubtful that the District has such individuals on staff and would, therefore, potentially need to hire outside consultants to review information submitted by the regulated community.

If any toxicity values are derived as a result of this regulation, they should be reviewed by an impartial, non-profit third party as considerable scientific judgment goes into developing toxicity criteria. Independent peer review is essential for obtaining standards and guidelines of the highest scientific quality. It will be important to minimize bias and potential conflict of interest by careful selection of reviewers.

7. **Section 4 Chronic Noncancer Risk Benchmark Determination Methodology**

Compliance with BACnc values should be determined based on annual average air concentrations, not 24-hour maximum air concentrations. An important feature of any air pollution standard is the treatment of exposure time. A 24-hour averaging period would be appropriate if the BACnc was based on acute health effects. However, since all of the BACnc values published in the draft regulations are based on chronic toxicity benchmarks, compliance should be determined based on annual average concentrations in the air, not 24-hour average or maximum air concentrations. Use of short term air concentrations to infer chronic, lifetime exposures will overestimate exposures that occur over a lifetime.

4.1 **Compliance with BACnc values that are based on U.S. EPA RfCs should be determined based on annual average air concentrations, not 24-hour maximum air concentrations.** As stated in the draft regulations, a BACnc is a concentration that is likely to be without an appreciable risk of deleterious effects during a “lifetime”. The BACnc (and the BACc) is intended as “chronic” risk benchmark. The requirement that compliance with a BACnc be determined based on a 24-hour maximum air concentration is inconsistent with the bases on which U.S. EPA RfCs are determined.

The primary source of toxicity benchmarks for BACnc values are U.S. EPA-derived RfCs. According to the “Methods For

Derivation Of Inhalation Reference Concentrations And Application Of Inhalation Dosimetry” (U.S. EPA, 1994), the RfC methodology requires conversion by dosimetric adjustment of the No Observed Adverse Effect Levels (NOAELs) and Lowest Observed Adverse Effect Levels (LOAELs) observed in laboratory animal experiments or in human epidemiological or occupational studies to human equivalent concentrations (HECs) for ambient exposure conditions. Per the guidance (U.S. EPA, 1994), these conditions are assumed to be 24 h/day for a lifetime of 70 years. According to the guidance (U.S. EPA, 1994), inhalation RfCs are relevant to those of any age and health status and are aimed at protecting the most sensitive members of the population, assuming **long-term continuous exposures**. In other words, RfCs are chronic toxicity benchmarks and, as such, they should be compared with average lifetime air concentrations, not short-term maximum air concentrations such as 24 or 8-hour maximum air concentrations. In evaluating potential chronic risk from hazardous waste combustion, U.S. EPA requires use of annual average vapor and particle phase air concentrations (U.S. EPA, 1998).

- 4.2** California RELs provide a secondary source of BACnc values under the draft regulations. **Compliance with BACnc values that are based on California RELs should be determined based on annual average air concentrations, not 24-hour maximum air concentrations.** This intent is illustrated in the “Air Toxics Hot Spots Program Risk Assessment Guidelines, Air Toxics Hot Spots Program Guidance Manual for Preparation of Health Risk Assessments (OEHHA, 2003). The “Air Toxics Hot Spots Program Risk Assessment Guidelines” indicate that chronic hazard quotients calculated under the California Air Hot Spots Program involves dividing the “annual average” air concentration by the chronic Reference Exposure Level (REL). In other words, under the California Air Toxics Hot Spots program, non-cancer chronic inhalation health impacts are calculated by dividing the substance-specific annual average air concentration in micrograms per cubic meter ($\mu\text{g}/\text{m}^3$) by the chronic inhalation REL ($\mu\text{g}/\text{m}^3$).

CRELs developed by the California Office of Environmental Hazard Assessment (OEHHA) should not be automatically adopted without evaluating their bases. See comment on Section 3.3.2.

Under the draft APD regulations, the sulfuric acid (H_2SO_4) BACnc is the concentration of sulfuric acid in air corresponding to

the California EPA's Chronic Reference Exposure Level (CREL) for sulfuric acid of $1 \mu\text{g}/\text{m}^3$. EPA has not developed toxicity factors for sulfuric acid, presumably because it has determined that sufficient toxicity information is not currently available.

Other state and Federal agencies have developed inhalation benchmarks for sulfuric acid as indicated in the table below:

STATE/ORGANIZATION	AVERAGING TIME (hr)	BENCHMARK ($\mu\text{g}/\text{m}^3$)
Arizona	1	22.5
	24	7.5
California	1	120
	Annual	1
Connecticut	8	20
	0.5 (30 min)	100
	24	50
Idaho	24	50
Kansas	Annual	2.38
Louisiana	8	23.8
Maine	0.25 (15 min)	300
	24	17
Massachusetts	24	2.72
	Annual	2.72
	8	24
Nevada	8	24
North Carolina	1	100

	24	12
North Dakota	1	30
	8	10
Oklahoma	24	100
South Carolina	24	10
Vermont	24	23.8
Virginia	24	17
Washington	24	3.3
Wisconsin	24	24
OSHA PEL		1000
NIOSH REL		1000
ACGIH TLV	8	1000

Data from: Agency for Toxic Substances Disease Registry (ATSDR) Toxicological Profile for Sulfur Trioxide and Sulfuric Acid (PB/99/122038)

The only two states that have developed annual benchmarks for sulfuric acid that correspond to the California REL, which is a chronic toxicity benchmark, are Kansas and Massachusetts. In each case, the allowable annual average concentration is higher than the California CREL that has been adopted as the BACnc under the draft regulations (2.4-fold and 2.7-fold, respectively). In addition to adopting the most conservative (i.e., lowest) air quality benchmark for sulfuric acid used across the U.S., the District has proposed that a 24-hr maximum air concentration be used to determine compliance with the 1 µg/m³ BACnc, even though compliance with the California CREL is intended to be determined based on an annual average according to the “Air Toxics Hot Spots Program Risk Assessment Guidelines, Air Toxics Hot Spots Program Guidance Manual for Preparation of Health Risk Assessments (OEHHA, 2003). As can be seen in the table, the proposed BACnc is also lower than every single other 24-hour benchmark listed. Clearly the District has gone to great lengths to

identify a highly protective health benchmark for sulfuric acid. However, the District should take note of the wide variability in the sulfuric acid benchmarks that are published by the various state and Federal agencies across the country as they consider arguments for a more flexible approach to evaluating whether compliance with a particular health benchmark has been demonstrated.

Human studies of sulfuric acid generally do not report toxic effects for sulfuric acid until much higher exposure concentrations than the California EPA's CREL (i.e., $1 \mu\text{g}/\text{m}^3$) are encountered. For example, workers in the lead battery industry showed etching and erosion of the teeth only after 4 months exposure to an average concentration of $0.23 \text{ mg}/\text{m}^3$ (i.e., $230 \mu\text{g}/\text{m}^3$) sulfuric acid (Gamble et al., 1984). This concentration is approximately 230 times higher than the CREL that has been adopted as the BACnc under the draft regulations.

This is another example of why broad adoption of air quality health benchmarks developed by other state agencies without evaluating their bases is ill advised. Additional examples may be provided upon request.

- 4.3 **Compliance with BACnc values that are based on U.S. EPA oral RfDs should be determined based on annual average air concentrations, not 24-hour maximum air concentrations for the reasons stated above.**
- 4.4 Michigan ITSLs are a fourth source of BACnc values under the draft regulations. **ITSLs developed by the Michigan Department of Environmental Quality should not be automatically adopted without evaluating their bases.** For example, an ITSL is listed as the BACnc for trivalent chromium on the Louisville Metro Air Pollution Control District (LMAPCD) Benchmark Ambient Concentrations and Associated *De Minimis* Values table.² According to the Michigan Department of Environmental Quality Air Quality Division List of Screening Levels (ITSLs, IRSLS SRSLS), the ITSL for trivalent chromium is based on a Threshold Limit Value (TLV) developed by the ACGIH. According to IRIS, "Occupational exposure to trivalent chromium and other chromium compounds by inhalation has been studied in the chromate manufacturing and ferrochromium

² http://www.apcd.org/star/bac_and_de_minimis.html.

industries; however, exposures all include mixed exposures to both Cr(III) and Cr(VI)... Data addressing exposures to Cr(III) alone are not available, and the occupational studies are considered to be unsuitable for development of an RfC for Cr(III).” Therefore, the Michigan ITSL for trivalent chromium should not be adopted by the District as a BACnc.

This is but one example of why broad adoption of air quality health benchmarks developed by other state agencies without evaluating their bases is ill advised. Additional examples may be provided upon request. See comments on Section 3.3.3 for additional comments on use of Michigan toxicity benchmarks.

4.5 It is recommended that the District reconsider the use of OELs for use as BACnc values under the proposed regulations.

Occupational Exposure Levels (OELs) are listed as a fifth source of BACnc values under the draft regulations. OELs are developed for workplace exposures that occur 8 hours per day, 5 days per week over a working lifetime. Continuous community exposure is different in several respects from workplace exposure. The total duration of community exposure is possibly longer: a full lifetime versus a working lifetime. Workplace exposures are intermittent, allowing time for recovery, clearance, and excretion, while worst-case community exposures are assumed to be continuous. Communities contain some individuals, including adults in poor health and children, who are more sensitive to pollutant effects than those who work.

TLVs have been sharply criticized for use in protecting workers, as the basis for OSHA PELs, and in developing state and local air concentration limits for HAPs. A sizeable fraction of TLVs were shown to be based partially or wholly on unpublished corporate communications (Castleman and Ziem, 1988). This study concluded that TLVs should not be considered to be thresholds of adverse effects. It is generally concluded that occupational exposure levels (OELs) should only be used with extreme caution to develop chronic acceptable air concentrations for use in evaluating community health effects. For example, U.S. EPA concluded in “Methods For Derivation Of Inhalation Reference Concentrations And Application Of Inhalation Dosimetry” (U.S. EPA, 1994) that the use of OELs for the derivation of RfCs is precluded stating that OELs often are not based on chronic effects and may differ from RfCs in severity of effect. The OELs further assume intermittent exposure periods of the workplace, whereas RfCs are set to protect against continuous exposure. Finally, OELs

may not incorporate the most current toxicological information because toxicological review is not conducted on a regular basis.

For the reasons listed above, it is suggested that OELs generally not be used as the basis of BACnc values. However, if the OEL documentation suggests that the OEL is a "reasonable surrogate" for a NOAEL or LOAEL and it is the only secondary data source available for an important compound, the following regression equation developed by Calabrese and Kenyon (1991) may be more accurate for relating TLVs to RfCs than the procedures outlined in the draft regulations:

$$\log_{10}(\text{RfC}) = -3.5 + 1.1 \log_{10}(\text{TLV}) \quad (R^2 \text{ of } 0.70)$$

where both RfC and TLV are expressed in $\mu\text{g}/\text{m}^3$.

4.6 The rationale for recommending use of 7-day inhalation NOAELs and LOAELs should be provided. Since BACnc values are intended to be protective of chronic exposure, NOAELs and LOAELs derived from a 7-day study should only be used with extreme caution. The time frame for the exposure is critical, because the safe dose (or the dose that produces some defined effect) may vary substantially with the length of exposure (<http://www.epa.gov/ttn/atw/toxsource/noncarcinogens.html>). The prediction of long-term effects from short-term observations is a questionable practice and should not be condoned as a general policy.

4.7 The statement "and data are not available to indicate that oral-route to inhalation-route extrapolation is inappropriate, then the oral NOAEL or LOAEL may be used to calculate the BACnc" Should be added. The differences in biological processes among routes of exposure (oral, inhalation, dermal) can be great because of, for example, first-pass effects and differing results from different exposure patterns.

4.8, 4.9, 4.10 LC50s and LD50s can be used legitimately to identify compounds that warrant further review but should not be used as the basis for chronic toxicity BACnc values. The mechanism by which a compound is lethal following short-term exposure to high concentrations is typically different from the mechanism by which that same chemical, in much lower concentrations, causes chronic toxicity.

Even if adjustment factors are applied to account for difference in exposure duration, acute toxicity values do not provide a good basis for reliable estimates of chronic toxicity. Lethality data do not accurately reflect the full spectrum of toxicity because some chemicals have low acute toxicity but produce serious long-term health effects. The toxic endpoint used in LD50 and LC50 studies (i.e., lethality) is not appropriate for establishing concentrations that are safe. A concentration that does not kill an animal is not the same as a concentration at which no adverse health effects are seen. Thus, LD50 and LC50 data are wholly inconsistent with the standard accepted methods for developing non-cancer health benchmarks. In addition, According to the “Guidelines for Developing Community Emergency Exposure Levels for Hazardous Substances”, the median lethal concentration should not be used as an absolute number because many extraneous factors, such as species, sex, age, and duration of exposure can influence or alter the precision of the number (CTNRC, 1993).

- 4.11 The District should not establish a default BACnc values for compounds that lack toxicity values developed by other reputable agencies.** The basis for the recommended default BACnc of $0.04 \mu\text{g}/\text{m}^3$ is unclear in the regulation and the District’s response to comments. According to the District’s response to comments, the BACnc of $0.04 \mu\text{g}/\text{m}^3$ is the 95th percentile value of over 10,000 chemicals in RTECs that any chemical would be environmentally acceptable. It is not clear from this explanation if the intent was to develop a yardstick value that is so high that any chemical concentration that exceeds it would almost certainly cause adverse health effects or if the value actually represents the 5th percentile, which would be extremely conservative. In addition to the failure to make clear what the value actually represents, the District has not indicated the statistical bounds on this default BACnc. If the goal is to be 95% confident that any chemical concentration that exceeds $0.04 \mu\text{g}/\text{m}^3$ does in fact pose a potential health threat, then a tolerance interval should be calculated rather than simply taking the 95 percentile of the data, keeping in mind that there are constraints on the data to be normally distributed. The District should, at a minimum, provide the Special Air Advisory Committee Report on the derivation of this default value that is referenced in the District’s response to comments for review so that the statistical validity of the value can be ascertained.

Even if it is determined that from a statistical perspective, such an approach is valid, assigning a default health criterion for application to a broad range of chemicals is without scientific merit

because each chemical has unique toxicological properties. While it is appropriate to err on the side of protection of health and the environment in the face of scientific uncertainty, common sense and reasonable application of assumptions and policies are essential to avoid unrealistic estimates of risk (U.S. EPA, 1995). This type of approach only serves to add more uncertainty and confusion to a process that is already amply endowed with both.

8. Section 5 Consideration of Acute Non-Cancer Effects

If the District plans to regulate chemicals on the basis of acute health effects, then the methodology that will be used should be explicitly stated in an updated proposed rule so that the procedures can be commented upon by the regulated community.

Regulation 5.21 Environmental Acceptability for Toxic Air Contaminants

Section 2 Ambient Goals and Standards for Environmental Acceptability for Toxic Air Contaminants

2.2.1 See general comment above on target cancer risk ranges.

2.2.2 See general comment above on target hazard quotients.

2.2.3 Order of magnitude jumps in target cancer risks would be more appropriate for setting limits on the EAL for all TACs. In addition, cancer risks should only be expressed to one significant figure. Given the many uncertainties that influence these estimates, regulating chemicals to a target cancer risk that is expressed to two significant figures (such as 3.8×10^{-6}) stretches the limits of accuracy of the equations and methods and seems arbitrary. It is recommended that the Point Source EAL risk be set to 1×10^{-5} instead of 3.8×10^{-6} .

2.5.1 See general comment above on target cancer risk ranges.

2.5.2 See general comment above on target hazard quotients.

2.5.3 Order of magnitude jumps in target cancer risks would be more appropriate for setting limits on the EAL for all TACs. In addition, cancer risks should only be expressed to one significant figure. Given the many uncertainties that influence these estimates, regulating chemicals to a target cancer risk that is expressed to two significant figures (such as 7.5×10^{-6}) stretches

the limits of accuracy of the equations and methods and seems arbitrary. It is recommended that the Point Source EAL risk be set to 1×10^{-4} instead of 7.5×10^{-6} .

Section 4 Demonstration of Environmental Acceptability and Compliance Plans for Permitted Stationary Sources

4.8.1 See general comments above on implementation of a tiered risk-based decision making approach. Implementation of a tiered approach that incorporates use of more refined risk assessment techniques in later phases of the evaluation would obviate the need to prepare many of these costly, labor-intensive Risk Reduction Plans.

4.8.3 The District is applauded for recognizing the importance of providing an opportunity for public review and comment of proposed Risk Reduction Plans. However, if the draft regulations are implemented in their current form, widespread non-compliance is likely to be the result and many Risk Reduction Plans will need to be written and reviewed. The preparation of these plans by the agency and the subsequent review and public commenting period will no doubt dramatically slow the permitting process. The District should seriously reconsider whether it currently has the resources and staff expertise to implement the draft regulations.

4.3.10 **The District should remove the statements about addressing synergistic toxic effects since there is no accepted methodology for doing so. If the district insists on leaving this language in the regulations, similar language about addressing potential antagonistic effects should be added.** While it is true that some pollutant combinations are antagonistic or synergistic (i.e. one pollutant nullifies or exacerbates the effects of another), no simple equation can be applied to evaluate risk of all such combined exposures where synergistic or antagonistic chemicals are involved.

4.12 The requirement that the permittee petition that an emission standard be revised if the benchmark ambient concentration becomes less stringent is overly burdensome to the permittee. The agency should automatically revise emission standards pertaining to constituents for which benchmark ambient concentrations becomes less stringent.

9. Regulation 5.22 Procedures for Determining the Maximum Ambient Air Concentration of a Toxic Air Contaminant

General Comment

Receptor Location The subject should have the opportunity to demonstrate that the area from the property line to the nearest receptor, or perhaps some default distance (whichever is closer) will not be used for any public purpose and is not productive for agriculture or wildlife. A reasonable approach would be to evaluate the maximum GLC at the fenceline as an initial screen. If those concentrations pass, then no further evaluation is warranted. If the fenceline concentrations exceed the BAC for any compound, then GLC at the maximally affected non-industrial receptor could be evaluated. This type of approach is consistent with other Air Toxics programs around the country such as the Texas Risk Reduction Program and the Residual Risk programs.

Section 1 The use of average emission rates for determining maximum concentrations for intermittent emission sources recognizes the difficulty in determining impacts for sources that do not emit on a continuous basis. However, the restriction for limiting these activities to not less than 10% of the maximum rate seems arbitrary. It is anticipated that numerous permit revisions to establish and or clarify nonspecific Regulation 5.20 limits would follow adoption of this wording. Although this language is perhaps a good screening approach for addressing the complexities involved in modeling intermittent sources, it may be overly simplistic for some analyses. Additional language allowing for more sophisticated treatment of intermittent source modeling in Section 5 upon the approval of the Air Pollution Control Board is requested.

Sections 2 and 3

Sections 2 and 3 address simplified methodologies (i.e. lookup tables) for determining maximum ambient concentrations. The lookup tables appear to yield very conservative (i.e. higher than expected) ambient concentrations. Unfortunately, the bases for developing these lookup table values were not available for this review and therefore detailed comments on these tables were not developed.

Section 4 Section 4 provides an option for use of U.S. EPA Screening Models for determining the maximum concentrations from toxic air toxics from a process or process equipment. This approach

may be useful on occasion but has limited applications. The U.S. EPA Screening models are designed for modeling single sources of emissions at a facility. Each emission source would need to be modeled independently and the sum of the concentrations summed without regard to time or locations of maximum concentrations to obtain site-wide impacts. This approach is overly conservative for most modeling scenarios. Additionally the U.S. EPA Screen models only predict hourly concentrations, which must be multiplied by an adjustment factor to obtain longer term concentrations.

Section 5 The overall approach of using a “Tiered Approach” for conducting ambient air quality evaluations is commendable, but of limited value due to the conservative assumptions incorporated in Sections 1 through 4. It is anticipated that the vast majority of the regulated community will conduct analyses described in Section 5. Therefore, the most detailed comments are provided for this section. Section 5 regulation requirements are not sufficient to efficiently set up an air dispersion model because the items referenced to the U.S. EPA *Guideline on Air Quality Models* (40 CFR 51, Appendix W) and *User’s Guide for the Industrial Source Complex (ISC3) Dispersion Models*, Volume 1 (EPA-454/B-95-003a) do not specify many important options as described in greater details below.

10. Sections 5.1 and 5.3 Specific issues regarding air dispersion modeling and suggestions for the improvements are provided below:

Comments or descriptions of various parameters to be better specified/defined in the regulation are identified and briefly described in this section. Suggestions for these comments are provided in the following section.³

1. There is no specification regarding inclusion of Dry/Wet Deposition to evaluate concentrations.

Suggestion: Confirm that the dry or wet deposition option is allowed to evaluate concentrations created by particulate sources, as necessary.

³ Specific comments and suggestions relating to modeling under the proposed STAR Program were developed in consultation with Sage Environmental Consulting. Resumes for Igor B. Shnayder, Project Manager, and Randy D. Pamley, P.E., Sage Environmental Consulting, are attached as Appendix 2 and 3, respectively.

2. There is no discussion on whether elevated terrain or flat terrain should be considered.

Suggestion: Flat Terrain option may be used in all modeling exercises based on the general terrain for the County. The APCD evaluations for the time required for a modeling setup (6 hours) implies that this option is appropriate.

3. If elevation terrain is required, it is important to specify the appropriate method for importing elevations from DEM files.

Suggestion: Linear interpolation method is to be authorized for all modeling exercises.

4. The District should specify whether long-term emissions rates be used in modeling of 8-hour and 24-average emissions instead of maximum potential hourly emission rates.

Suggestion: Most facilities cannot and do not sustain the maximum processing rate for any prolonged period of time. For annual and 24-hour average BAC's and, possibly, for 8-hour average BAC's, more realistic emission rate estimates should be used.

5. There is no discussion whether emission rate adjustments will be acceptable.

Suggestion: Hourly, monthly, seasonal, and other adjustments to the point source emission rates and wind speed-dependent emission rates for fugitive particulate sources should be allowed for inclusion in modeling.

6. Impacts from low-height, low-buoyancy sources are greatly overestimated during calm weather conditions because the model does not take into account plume meandering. Other states' modeling guidelines authorize reasonable conservative adjustments to the predicted impacts.

Suggestion: 0.6 emission rate adjustments for low-level fugitive and pseudo-point sources should be authorized consistent with the other states' modeling guidance documents (an example modeling memorandum created by the Texas Air Dispersion Modeling Team leader is provided).

7. The District should specify whether the property line boundary receptors should be placed on the fence line or the property line.

Suggestion: Property line should represent the nearest outside receptors for a facility if the property line is different from the fence line.

8. There is no discussion about the Cartesian Receptor Grids to be used in the model. How far should the receptors be placed from each other?

Suggestion: The property line discrete receptors may be located 100 meters or less apart. Discrete or Cartesian grid receptors may be spaced 100 meters apart from the property line to approximately 500 meters from the emission sources. For distances from 500 m to 3 kilometers from the emission sources, 500-meter distance is sufficient and for distances exceeding 3 kilometers from the emission sources 1,000-meter distance between the receptors is sufficient. The grids must not extend beyond 10-kilometer distance from the emission sources.

9. The District should specify whether any special discrete receptors be used in the model.

Suggestion: The regular grid receptor design described above should be sufficient to evaluate toxic substance impacts. The APCD evaluations for the time required for modeling setup (6 hours) implies that no special discrete or flagpole receptors should be considered.

10. The District should specify if there should be any receptors placed beyond the County Line to evaluate the impacts outside the Jefferson County.

Suggestion: Since the STAR Program was created for the Jefferson County, receptors beyond the county line must not be included in the modeling.

11. There is no discussion regarding the number of years of meteorological data to be used in modeling demonstrations.

Suggestion: One full year of meteorological data should be more than sufficient to determine which chemicals will be subject to the

STAR program compliance. One-year modeling will result in 8,760 to 8,784 calculated concentrations for each receptor. Both Michigan and Texas only require one year of data for air toxics demonstrations (Michigan Air Use Permit Technical Manual, Tab 9, p. 22; (Modeling and Effects Review Applicability: How to Determine the Scope of Modeling and Effects Review for Air Permits.

12. The District should specify the year of the meteorological data that should be used in the modeling.

Suggestion: Any available meteorological data file containing at least 8,760 hours of meteorological information (including pre-processed calm hours), should be considered valid for the demonstration of the STAR program compliance.

13. There is no discussion on which meteorological stations (surface station and the upper air station) should be used in modeling for the Jefferson County.

Suggestion: A combination of the data for the surface station located in Louisville, KY (station number 93821) and the upper air station in Wright Patterson, OH (station number 13840) should provide reasonable impacts evaluation.

14. Sections 5.1 and 5.2 do not discuss in sufficient detail or provide a justification for the maximum predicted concentrations range. The District should specify whether usage of High-1st-High values is the only option for the STAR Program compliance demonstration.

Suggestion: For annual average values, only High-1st-High values should be used. More flexibility should be provided for short-term impact evaluations, either by authorizing to use High-2nd-High, High-3rd-High, etc. values or by authorizing specific maximum number of exceedances of the BAC for any specific receptor depending on the location of the receptor in an industrial/undeveloped or a residential area.

15. A method to evaluate the number of exceedances for a receptor is not discussed for occurrences of exceedances of the BAC level specified in the regulation. The District should specify whether the "Maxifile" output option will be required for inclusion in the modeling setup file.

Suggestion: Under the currently proposed regulations, only the highest predicted concentration is allowed to be used in demonstrating compliance. However, if some number of exceedances is allowed under the final regulation, Maxfiles may provide a useful tool to demonstrate compliance with different program levels.

16. There is no discussion regarding files used to plot the location of maximum predicted concentrations. The District should specify whether the "Plotfile" output option will be required for inclusion in the modeling setup file.

Suggestion: Under the currently proposed regulations, only the highest predicted concentration is allowed to be used in demonstrating compliance. However, if some number of exceedances is allowed under the final regulations, Maxfiles may provide a useful tool to demonstrate compliance with different program levels

* * * * *

These are but a few notable examples of the vagueness and uncertainties inherent in the proposed STAR Program. Other examples may be presented to the Board at its request. In short, LG&E believes that the proposed STAR Program is not scientifically or technically sound and, as a result, the risk methodology proposed for use in the STAR Program will overestimate the risk posed to a resident living near a source. Such overestimation will result in expensive actions to reduce the amount of air toxics emitted by a stationary source with no relation to actual risk.

B. The Proposed STAR Program Is Contrary to U.S. EPA's Risk Management Policy and Selectively Uses Methodologies From Other State Air Toxics Programs

1. U.S. EPA Risk Management Policy

U.S. EPA's risk management policy "strives to provide maximum feasible protection against risks to health from hazardous air pollutants by (1) protecting the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1 in a million [1×10^{-6}] and limiting to no higher than approximately 1 in 10 thousand [1×10^{-4}] the estimated risk that a person living near a plant would have."⁴ This federal risk management policy, which was established under the Benzene NESHAP, provides for the protection of public health with an "ample margin of safety" as required under the Clean

⁴ *Residual Risk: Report to Congress*, March 1999 (EPA-453/R-99-001), p. ES-11.

Air Act.⁵ The District, without more explanation or justification, states that it “does not consider U.S. EPA’s allowed risk policy to be sufficiently protective of public health.”⁶ Consequently, the District established a goal of 1×10^{-6} for a single carcinogen from a single process as the basis for the proposed STAR Program.⁷

Absent some compelling reason, any air toxics program developed by the District should be consistent with U.S. EPA’s risk management policy. Such consistency will ensure protection of human health with an ample margin of safety while providing certainty to regulated industries that might otherwise be required to implement and achieve compliance with two separate air toxics programs.

LG&E respectfully requests that the Board require the District to provide a full explanation of the basis upon which it determined that U.S. EPA’s risk management policy is not sufficiently protective of human health.

2. Selective Use of Methodologies From Other State Programs

The District defends the soundness of the proposed STAR Program by reference to methodologies and programmatic components adopted from other state air toxic regulations and incorporated into the proposed STAR Program.⁸ Such methodologies and programmatic components were not, however, incorporated as a whole or without revision.

Consider, for example, the following components of Michigan’s air toxics program, from which many components of the proposed STAR Program, were taken, and which are not included in the proposed regulations:⁹

- Michigan’s program does not apply to existing sources.
- It provides exceptions from applying T-BACT (Best Available Control Technology for Toxics), for emissions units that emit only toxic air contaminants that are particulates or VOCs, and are in compliance with best available control technology (“BACT”) or lowest achievable emission rate (“LAER”) requirements for particulates and VOCs or for emissions units that meet standards which have been promulgated under Section 112(d) of the Clean Air Act or for which a control

⁵ *Id.* at ES-12. See also Clean Air Act Section 112(f), which sets forth EPA’s responsibilities in regulating Residual Risk.

⁶ Response to Comment 5.21-12; see also PRIA, p. 3, which includes a discussion of U. S. EPA’s risk management policy but does not include a discussion of the basis upon which the District determined that U.S. EPA’s risk management policy was insufficient.

⁷ PRIA, p. 12.

⁸ Response to Comment Overall-8, p. Overall-3.

⁹ Michigan R.224 *et seq.*

technology determination has been made under Section 112(g) of the Clean Air Act with certain conditions.¹⁰

- It allows emissions up to ten times higher than the applicable standards on industrial properties and public roadways.¹¹
- It establishes a policy by which a default value of 0.1 µg/m³ for noncarcinogens rather than the 0.04 µg/m³ default value developed by the District for noncarcinogens in the proposed STAR Program, may be used in evaluating risk. There is no default value for cancer in Michigan's program.¹²

None of the components listed above from the Michigan program are included in the proposed STAR Program.

As another example, consider Texas' Chapter 115-Control of Air Pollution from Volatile Organic Compounds, Subchapter H: Highly Reactive Volatile Organic Compounds, Division 3: Fugitive Emissions §§115.780 *et seq.*, which serves as the basis for proposed Regulation 1.21, Leak Detection and Repair. Texas' regulation narrowly targets a handful of sources emitting a limited number of highly-reactive volatile organic compounds.¹³ Significant exemptions are provided for components determined by Texas to have a low probability of leaking.¹⁴ The District's regulation, which applies to sources subject to a federal LDAR program and any other source that the District determines may pose a threat to human health or the environment, applies to organic and inorganic compounds, a virtually endless list of chemicals, and contains no exemptions.¹⁵

By selecting some, but not all, components from different state programs and combining those components into a new regulatory program, the District has created a brand new regulation, the soundness of which cannot be established by reference to a now dissimilar state air toxics programs. As a matter of statute, the District is required to independently assess the soundness of the proposed STAR Program although it has not done so.¹⁶ Absent such an assessment, it is difficult to understand how the District determined that the standards proposed under the STAR Program are "rigorous but achievable."¹⁷

It is the Board's responsibility to ensure that regulations adopted by the District are both reasonable and necessary¹⁹ LG&E respectfully request that the Board fully evaluate the necessity and reasonableness of the STAR Program as proposed by the District and adopt

¹⁰ **Michigan R. 224.**

¹¹ Michigan R.225.

¹² Michigan Air Use Permit Technical Manual, Tab 6, p. 11; see also Michigan R.232, which establishes the procedures by which the value for noncarcinogens may be developed.

¹³ Texas Chapter §115.780.

¹⁴ Texas §115.787.

¹⁵ See Regulation 1.21.

¹⁶ See Regulation 1.08 Section 7, which sets forth the requirements to be addressed in the PRIA.

¹⁷ See Response to Comment Overall-8, p. Overall 3, which states

¹⁹ See, generally, KRS Chapter 77 *et seq.* and Regulation 1.08 Section 7.

only those provisions that are demonstrated to be necessary to address emissions in Louisville Metro.

II. The Scope of the Regulatory Program

In addition to the risk based program established in Part 5 of the proposed STAR Program, the regulations establish significant new regulatory requirements.

A. Chemicals of Concern

LG&E recommends that the manner in which Category 1, 2, 3 and 4 Toxic Air Contaminants (“TAC”) are regulated be reconsidered by the Board.

As initially envisioned in the Risk Management Plan for the West Louisville Air Toxics Study (WLAT Study), chemicals of concern and their sources were to be identified. As a result, 18 chemicals of concern were identified as part of the WLAT Study, and are regulated under the proposed STAR Program as Category 1 TACs. In addition to the 18 Category 1 TACs, the District added 19 additional TACs as Category 2 on the basis of U.S. EPA’s September 27, 2002 Relative Risk Screening Analysis. U.S. EPA’s Relative Risk Screening Analysis, notes the following:

- The Relative Risk Screening Analysis is a “20,000 foot view” of potential impacts of toxic air pollution in the Southeast.
- The Relative Risk Screening Analysis does not “imply any cause-effect relationship between an actual case of disease or death and potential exposure.”
- The Relative Risk Screening Analysis is based on RSEI data for TRI emissions from 1999 and NATA data from 1996.

Because the Relative Risk Screening Analysis was not intended as a source of regulatory decision-making, it does not justify regulating Category 2 TACs in the same manner as Category 1 TACs.¹⁸ None of the 19 additional chemicals were identified above a regulatory level of concern in the WLAT Study. Moreover, the data used by U.S. EPA at the time it analyzed relative risk in the southeast does not take into account industry emission reductions or changes in mobile emissions that have occurred in the last eight years. For example, between 1999 and 2002, industry in Jefferson County reduced emissions to the air by over four million pounds.

¹⁸ A thorough analysis of the Relative Risk Screening Analysis, which was prepared by Kenneth Mitchell, Ph.D, one of the authors of the Relative Risk Screening Analysis, and presented to the State Air Toxics Work Group on January 26, 2005.

Because there is no demonstrated health risk nor, as yet, identified health benefit to controlling Category 2 TACs in the same manner as Category 1 TACs, Category 2 TACs should be regulated under the proposed STAR Program as urban air toxics, Category 3, or as Hazardous Air Pollutants (“HAPs”), Category 4, in accordance with their listing as such by U.S. EPA. Chemicals, such as copper, ammonia, aluminum and sulfuric acid, which are neither a Category 1 TAC, an urban air toxic nor a HAP should not be included in the STAR Program at all.¹⁹

B. Regulatory Uncertainty

As a general matter, the purpose of adopting administrative regulations is to make the laws an agency enforces clearer and more specific for the regulated community. Such regulations also establish the procedure or organization necessary for an administrative agency to meet its statutory obligations. LG&E recommends the Board reconsider the following regulatory provisions:

1. Enhanced Reporting Obligations for CY 2004 Emissions

Under Regulation 1.06 Section 5.2.1.1.1, the District is requiring Title V companies to report enhanced emissions data for CY 2004 by July 15, 2005, including the uncontrolled emission rate for each listed toxic air contaminant, including the maximum hourly and daily emission rates, along with the current actual annual and average hourly and daily emission rates. LG&E is deeply troubled by the retroactive effect of this section. Current District regulations require annual emissions inventory submissions for HAPs, however, that information is submitted as a plant-wide emission total, without regard to rate of emission.

In assessing the new burdens added under the proposed STAR Program, the District states that it “considers that much of the enhanced emissions data are already being tracked” as part of the Toxics Release Inventory (“TRI”) Program.²⁰ Thus, the District has justified adding new, and retroactive, reporting requirements on the basis of an assumption. TRI only covers 667 chemicals and chemical categories.²¹ The proposed STAR Program covers only 190 chemical but thousands of associated compounds. Only annual emissions are required to be reported under TRI – regardless of when during the year they were emitted. Under the proposed STAR Program, emissions must be reported in actual hourly, maximum hourly, and daily emission rates for each listed TAC. This is substantially more information than that tracked for TRI.

LG&E recommends that the companies be given a short period of time following the effective date of the regulation in which to make arrangements for the collection of the required data. To that end, we recommend that the Board amend Section 3 to provide

¹⁹ If the Board adopts LG&E’s recommendation, Category 3 and Category 4 TACs will become Category 2 and 3 TACs, respectively.

²⁰ PRIA, p. 15.

²¹ See, for example, <http://www.epa.gov/tri/chemical/>.

that the collection of the new data required by this regulation shall commence 90 days after the date of the regulation.

2. The manner in which chromium is addressed in the proposed STAR Program should be clarified.

Chromium is a metallic element that naturally occurs in the environment in two major valence states: trivalent chromium (often referred to as chromium III) and hexavalent chromium (often referred to as chromium VI). For that reason, chromium may be speciated and identified as trivalent chromium, which is an essential element in humans with a daily intake of 50 to 200 micrograms per day recommended for an adult, or hexavalent chromium, a much more toxic form than trivalent chromium and which has been identified as a known human carcinogen.²² Sources that may emit chromium in Louisville Metro include paint and chemical manufacturing operations, chromium plating, steel production and processing operations, cement production, cooling towers, and coal and oil combustion.

a. Chromium should not be listed as a Category 1 TAC.

It is our understanding that the District has included “chromium and chromium compounds” in the list of Category 1 TACs based on the West Louisville Air Toxics Study (“WLATS”). The monitoring that was done for chromium as part of the WLATS was for total chromium. However, for purposes of the risk analysis, all of the chromium was assumed in the WLATS to be hexavalent chromium. Because the WLATS assumes that all the total chromium measured at the monitors is hexavalent, it overestimates the toxicity of the chromium present in the ambient air. Consequently, because the WLAT Study did not speciate chromium as trivalent or hexavalent, there has been no demonstration that either trivalent chromium or hexavalent chromium is actually a health risk. For that reason, hexavalent and trivalent chromium should not be included as a Category 1 TAC in the STAR Program, but should be included as an urban air toxic and added to the list of Category 3 TACs.

3. The proposed STAR Regulations do not provide a basis upon which chromium may be speciated.

The proposed STAR regulations do not clearly indicate the form – total, hexavalent or trivalent – in which chromium is to be evaluated for environmental acceptability nor do the proposed regulations establish a method or guidance by which chromium may be speciated.

a. The proposed regulations do not clearly identify the form of chromium to be evaluated.

²² See 69 FR 55218, 55221 (National Emission Standards for Hazardous Air Pollutants for Industrial, Commercial, and Industrial Boilers and Process Heaters, Final Rule) (September 13, 2004).

Chromium is listed as a Category 1 TAC in the proposed Regulation 5.23 Section 1.2 by reference to the Chemical Abstract Service (“CAS”) No. 7440-47-3 & various. CAS No. 7440-47-3 is the registry number for elemental chromium, i.e., total chromium. U.S. EPA’s IRIS Database, which provides unit risk estimates for cancer causing chemicals and inhalation references for non-cancer causing chemicals for use in calculating Benchmark Ambient Concentrations per proposed Regulation 5.20, only includes risk information for trivalent chromium, CAS No. 16065-83-1, and hexavalent chromium, CAS No. 18540-29-9. Because the list of Category 1 TACs proposed by the District specifically references the CAS number for total chromium, it is not clear what form of chromium is required to be evaluated for environmental acceptability under the proposed regulations.

It appears it is the District’s intent to evaluate chromium under the STAR Program as either trivalent or hexavalent chromium. The District has posted a list of Benchmark Ambient Concentrations (“BACs”), which provides the BACs for “chromium hexavalent & chromium compounds, CAS No. 7440-43-9” and “chromium trivalent & chromium compounds, CAS No. 16065-83-1” on its website. This appears to indicate that a source may speciate its emitted chromium and evaluate the risks from trivalent chromium and hexavalent chromium separately. Whether chromium is to be evaluated as either trivalent or hexavalent chromium, or is to be evaluated as total chromium, with the assumption that all of the total is hexavalent chromium, should be clarified in the STAR Program.

b. The STAR Program should provide a regulatory method or guidance by which chromium may be speciated.

The proposed STAR regulations do not provide clear direction by which a source may speciate its emitted chromium as either trivalent and hexavalent chromium. Chromium is a trace element common in most coals and oils in minor amounts. The amount of chromium emitted to the atmosphere during coal combustion depends on various factors, including (1) the chromium content of the coal burned; (2) the type of boiler used and its firing configuration; (3) the portioning of chromium between fly ash and bottom ash; and (4) the chromium removal efficiency of any controls present on the unit.²³

If the District intends to allow a source to evaluate trivalent and hexavalent chromium, the District must provide a method by which a source can speciate the chromium it emits. Consider these two factors:

1. AP-42, Table 1.1-18 includes a hexavalent chromium factor of 7.95×10^{-5} lbs/ton of coal burned (controlled). Using the AP-42 chromium factor, hexavalent chromium would account for 30.38% of the total chromium

²³ Locating and Estimating Air Emissions From Sources of Chromium, U.S. EPA Office of Air Quality, Planning and Standards, EPA-450/4-84-007g, p. 147.

emitted from coal combustion. The 7.95×10^{-5} factor, however, has a rating of “D”, i.e., below average, on the basis that “the factor is developed from A, B and/or C-rated test data from a small number of facilities, and there may be reason to suspect that these facilities do not represent a random sample of the industry. There also may be evidence of variability within the source population.”²⁴

2. U.S. EPA in its 1998 *Study of– Final Report to Congress*, assumed that 11% of the total chromium emitted from coal-fired utilities is the more toxic hexavalent form.²⁵ U.S. EPA based its assumption that 11% of total chromium emitted from coal-fired boilers was hexavalent chromium on an analysis of the average annual emissions from a limited number of coal-fired sources with hexavalent chromium emissions ranging from 0.3% to 34%.²⁶ Under a 1994 report, entitled *Electric Utility Trace Substances Synthesis Report* (November 1994), which documents a study that paralleled U.S. EPA’s *Hazardous Air Pollutant Emissions from Electric Utility Steam Generating Units* and which was conducted by the Electric Power Research Institute (“EPRI”), 5% of chromium emissions were assumed to be hexavalent.²⁷ The AP-42 factor for speciating chromium is consistent with these ranges.

Absent a regulatory method or guidance by which chromium may be speciated, a regulated source is left with the District’s “hint” that chromium may be speciated. To avoid confusion, the STAR Program should be amended to clearly identify the manner in which chromium may be speciated.

4. Exposure from Routes Other Than Direct Inhalation

Following the informal comment period, the District added the following provision to Regulation 5.21 Section 4.10:

If the District determines that the presence of 2 or more TACs, at concentrations that comply with the EA levels in Sections 2.2, 2.5, and 2.8, would result in a synergistic or additive toxicological effect that may adversely affect human health, or that there is human exposure from routes

²⁴ AP-42, Volume 1, Fifth Ed. – January 1995, p. 10.

²⁵ See *Study of Hazardous Air Pollutant Emissions from Electric Utility Steam Generating Units – Final Report to Congress*, Volume 1, Table 6-1: Summary of High-End Risk Estimates from Chronic Inhalation Exposure by HAP for 424 U.S.Coal-Fired Utilities, p. 6-3.

²⁶ See *Study of Hazardous Air Pollutant Emissions from Electric Utility Steam Generating Units – Final Report to Congress*, Volume 1, Table 6-1: Summary of High-End Risk Estimates from Chronic Inhalation Exposure by HAP for 424 U.S.Coal-Fired Utilities, p. 6-4 (citing limited speciation data described in Appendix H of the EPA Interim Final Utility Report, Volume III).

²⁷ See *Study of Hazardous Air Pollutant Emissions from Electric Utility Steam Generating Units – Final Report to Congress*, Volume 1, p. ES-26.

other than direct inhalation, then the District shall prepare a proposed Risk Reduction Plan and the procedures specified in section 4.8 shall be followed. Board may, after providing an opportunity for public review and comment, require additional reductions of those toxic air contaminants from the contributing processes and process equipment. Any more stringent emission standard, and a schedule for complying with this emission standard, shall be an enforceable requirement of the applicable District permit for the affected process and process equipment.

The District has not proposed any administrative procedures by which it would evaluate human exposure from routes other than direct inhalation. It has not evaluated the need to add this provision in the PRIA nor has it requested staff or funding necessary to make such an evaluation²⁸ For these reasons, LG&E requests that the Board delete this provision from Regulation 5.21 Section 4.10.

5. Applicability of Proposed Regulation 1.21, Enhanced Leak Detection and Repair

Under Regulation 1.21 Section 1.1.2, a process unit for which the District determines the implementation of a leak detection and repair (LDAR) program is appropriate may be deemed an “affected facility” and thereby become subject to regulation.

Based on our review of the PRIA, proposed Regulation 1.21 only applies to sources already subject to the federal LDAR program. See, for example, PRIA, page 7, which states that any process unit already subject to the federal LDAR program will be subject to the regulation, page 10 which states that the new regulation will require affected facilities to comply with more stringent leak detection than would otherwise be required and page 16, which states that the program will specifically apply to ten companies.

LG&E recommends that the Board clarify Regulation 1.21 Section 1.1.2 to specify that it applies only to processes or process units at sources already subject to the federal LDAR program.

6. Regulation 1.07, Excess Emissions During Startup, Shutdown and Malfunctions, and Regulation 1.20, Malfunction Prevention Program.

a. Regulation 1.07, Excess Emissions During Startup, Shutdown and Malfunctions

²⁸ See PRIA, pp. 8, 11, 17-21.

The District has revised Regulation 1.07, Excess Emissions from Startups, Shutdowns and Malfunctions on the basis that the current regulation “provides an automatic exemption from being deemed a violation if certain reporting requirements are met” and is, therefore, inconsistent with U.S. EPA’s Policy on Excess Emissions During Malfunctions, Startup, and Shutdown.²⁹ U.S. EPA’s policy regulates emissions of hazardous air pollutants (“HAPs”), including those contained in volatile organic compounds or particulate matter. The toxic air contaminants regulated under the proposed STAR Program include those listed by U.S. EPA as HAPs.

In accordance with its understanding of U.S. EPA’s policies, the District has revised the current regulation to

- delete provisions providing for emergencies, an affirmative defense;
- deem excess emissions violations without due process notice;
- define “malfunctions” without regard to sudden or unavoidable breakdowns and “excess emissions” by a specific emission rate and
- require numerous reports with prescriptive detail.

i. Deletion of Affirmative Defense

Under U.S. EPA’s Policy, “automatic exemptions” means “a generally applicable provision in a SIP that would provide that if certain conditions existed during a period of excess emissions, then those exceedances would not be considered violations.”³⁰ As a result, all periods of excess emissions are considered violations by U.S. EPA.³¹ But U.S. EPA’s September 20, 1999 Policy also states the following:

- The imposition of a penalty for excess emissions during malfunctions caused by circumstances entirely beyond the control of the owner or operator may not be appropriate.

-States may, therefore, as an exercise of their inherent enforcement discretion, choose not to penalize a source that has produced excess emissions under such circumstances.

²⁹ PRIA, p. 7.

³⁰ Policy on Excess Emissions During Malfunctions, Startup, and Shutdown, September 20, 1999. (Attachment).

³¹ *Id.*

- If approved into a SIP, an affirmative defense would be available to sources in an enforcement action seeking penalties brought by the state, U.S. EPA or citizens.³²

Affirmative defenses are not prohibited by U.S. EPA Policy. Such affirmative defenses are included in 40 CFR §70.6(g) and should be included here. We therefore recommend that, consistent with U.S. EPA policy, the Board revise proposed Regulation 1.07 to include a provision by which a source may assert an affirmative defense consistent with U.S. EPA's policy.

ii. Due Process Violations

According to U.S. EPA's February 15, 1983 Policy, "[a]ny malfunction provision must provide for the commencement of a proceeding to notify the source of its violation and to determine whether enforcement action should be undertaken for any period of excess emissions."³³ Notice of the finding of a violation and the opportunity to defend against such a finding is a basic tenet of due process. The District's proposed regulation does not provide a process by which a source is notified of its violation or by which the District may determine whether an enforcement action should be undertaken. Instead, it only provides guidance by which civil penalties may be imposed, a violation being a foregone conclusion.³⁴ The decision whether to impose civil penalties – or not – is not the same as determining whether an enforcement action should be taken in the first place. Nothing in U.S. EPA's Policies require that the District neither abdicate its enforcement discretion nor violate due process. The Board must, therefore, amend Regulation 1.07 to include procedures by which the District will make a determination that a violation occurred and notify a facility of its determination.

iii. Distinctions between "malfunctions" and "excess emissions"

As currently defined by U.S. EPA and previously defined by the District, "malfunction" means, in relevant part, "a sudden and unavoidable breakdown of process or control equipment."³⁵

Under the proposed STAR Program, the District has revised the definition of "malfunction" to mean "the failure of air pollution control equipment or process equipment or of a process to operate in a normal or usual manner that causes, or is likely to cause, emissions that exceed an applicable emission standard."³⁶ As a result, all startups and shutdown events are, by definition, "malfunctions," not just those resulting

³² *Id.* at pp. 1-2.

³³ Policy on Excess Emissions During Startup, Shutdown, Maintenance, and Malfunctions, February 15, 1983, p. 2.

³⁴ Proposed Regulation 1.07 §2.3.

³⁵ **40 CFR 60.2**; Regulation 1.07 §1.2.

³⁶ Proposed Regulation 1.02 §1.41.

from the sudden and unavoidable breakdown of process or process control equipment, even though U.S. EPA acknowledges that startups and shutdowns are part of a source's normal operation.³⁷ This definition is clearly contrary to the definitions used by U.S. EPA to regulate sources. As a result, the District's definition should be changed to be consistent with that used by U.S. EPA³⁸

The District has also revised the definition for "excess emissions" to include a secondary standard by which a source may determine whether excess emissions occurred if there is not an applicable emission standard for a toxic air contaminant established pursuant to Regulation 5.21 *Environmental Acceptability for Toxic Air Contaminants*, as follows.

"for the purpose of the notification and reporting requirements of Regulation 1.07 Excess Emissions During Startups, Shutdowns, and Malfunctions, excess emissions shall also mean emissions that exceed 125% of the reported actual maximum hourly emission rate of a toxic air contaminant that results from a startup, shutdown, or malfunction."³⁹

Defining excess emissions as those occurring above a certain percentage is simply arbitrary. The District has made no demonstration that those emissions – or those that exceed that arbitrary limit – are harmful to public health. Moreover, it may, as a secondary standard, violate U.S. EPA's policy as an automatic exemption.

Because the District's definition for malfunction and excess emission appear to contradict U.S. EPA policy and include arbitrary provisions, we respectfully request that the definitions for "malfunctions" and "excess emissions" be revised consistent with U.S. EPA's policies and definitions.

B. Regulation 1.20, Malfunction Prevention Program

In the PRIA, the District states that Regulation 1.20 is a new regulation.⁴⁰ It is, in effect, not new, but an expansion of existing Regulation 1.07 §4.2, which, for cases where malfunctions were of a repetitious nature, or when more than 12 failures of the same or similar pieces of equipment occur in a 12 month period, required the submission of a written program outlining a time schedule and corrective actions which would result in a permanent solution to the problem.

Unlike Regulation 1.07 §4.2, which clearly identified when the requirement to implement a malfunction prevention program applied to a process or process equipment, proposed

³⁷

³⁸ Policy on Excess Emissions During Startup, Shutdown, Maintenance, and Malfunctions, February 15, 1983, p. 1.

³⁹ Proposed Regulation 1.02 §1.30.

⁴⁰ PRIA, p. 7.

Regulation 1.20 applies in any of the following situations:

1. a malfunction involving the process or process equipment was reported pursuant to Regulation 1.07 and the District determines that the development and implementation of a malfunction prevention program is appropriate;
2. The District determines that a malfunction involving the process or process equipment may have occurred and that the development and implementation of a malfunction prevention program is appropriate; or
3. The District determines that the development and implementation of a malfunction prevention program is appropriate to minimize the likelihood of the occurrence of a malfunction that may become harmful to public health or welfare.⁴¹

Regulation 1.20 must be revised to clearly identify the standards and administrative procedures by which the District will require the preparation and implementation of a malfunction prevention program. To provide such necessary certainty, we recommend revising Regulation 1.20 to apply only to facilities where the District determines that malfunctions are of a repetitious nature, or when more than 12 failures of the same or similar pieces of equipment occur in a 12 month period, consistent with former Regulation 1.07 §4.2.

IV. Direct and Indirect Economic Impact of the Proposed STAR Program

Based on our review of the proposed STAR Program and the costs evaluated by the District in the PRIA, we are concerned that the costs associated with the program are uncertain. For example, it is unclear in the PRIA whether the District evaluated costs associated with adding controls to new or existing facilities. As a general matter, costs associated with adding new pollution control equipment at existing facilities are higher than costs associated with constructing air pollution control equipment at a new facility, due largely to site constraints, existing equipment placement and existing air pollution controls.

As another example, consider the costs associated with controlling sulfuric acid, a Category 2 TAC under the proposed STAR Program, which is emitted as a by-product of air pollution control equipment designed to control emissions of NO_x. Sulfuric acid was not identified as posing a threat to human health in the WLAT Study, i.e., a Category 1 TAC. Sulfuric acid is neither an urban air toxic, Category 3 TAC, nor a hazardous air pollutant, Category 4 TAC. Yet based on our current understanding of the proposed

⁴¹ Regulation 1.20 §1.

STAR Program, LG&E's cost to control emissions of sulfuric acid, a Category 2 TAC, in Louisville Metro range from \$20 million dollars to \$700 million dollars, depending on the control technology selected. These costs do not include associated operational and maintenance costs, which, again depending on the technology, may reach \$1 million dollars per year per unit.

A. Direct Costs

1. Permit Fees and Costs for Fiscal Year 2006

LG&E urges the Board to require the District to explain how the proposed STAR Program will be funded in Fiscal Year 2006 as required by Regulation 1.08 Section 7. If it will be necessary to increase fees on the regulated entities in Fiscal Year 2006, the District should state that now and provide an estimate of what increase in fees will be necessary to fund the proposed program through at least 2012, the anticipated period during which the STAR Program will be implemented. This information is critical for a full and fair evaluation of the direct costs associated with the proposed program.

3. Operational and Personnel Compliance Costs

LG&E is committed to environmental compliance. However, LG&E is concerned that if the District evaluated other state programs to develop the operational and personnel costs in the PRIA, the District's evaluation may underestimate the costs necessary to implement the proposed STAR Program due to the differences between the programs as implemented in their home state and as proposed for implementation in Louisville Metro. To the extent that the costs assessed by the District are based on other state program, such costs programs would, at this point, simply be too general to fully evaluate costs associated with the proposed STAR Program. The STAR Program proposed by the District is distinct from the state air toxic programs upon which it may be modeled. For that reason, LG&E recommends that the Board evaluate the basis for the District's cost assessment and, if based on other state programs, require the District to re-assess the cost of the proposed STAR Program as it is to be implemented.

B. Indirect Costs

The proposed STAR Program will require dedicated implementation by the District. Even with the addition of the 5 new staff members to implement the proposed STAR Program, the regulatory framework that is established in the proposed regulation will likely overwhelm the District's other staff, whose responsibilities include permitting, inspections and compliance.

Consider, for example, the requirements associated with the new malfunction reporting requirements established under the proposed STAR Program.

Under proposed Regulation 1.07, at least three reports, each containing detailed technical and operational information, must be submitted at specific times to comply with the proposed regulation. Each report and each report element established in the proposed regulation represents a requirement that the District must ensure compliance with. The District intends to do this with no additional staff or infrastructure. More importantly, the District intends to do this without any demonstration that the reporting requirements under the proposed regulation will actually result in any additional benefit to public health.

Given that 4,193 such excess emission events, including malfunctions, emergencies, start-ups and shutdowns were reported to the District between 1996 and October 2003, *see Courier Journal*, Dec. 21, 2003, it is apparent that hundreds of reports will be filed with the District. On average, 524 malfunction, emergency, start-ups and shutdowns were reported annually during that time frame. Taking that average, 1,572 reports may be submitted to the District under the proposed STAR Program annually, each requiring review and analysis by existing District staff, who also are responsible for issuing permits, inspecting facilities, and other duties. Even without these new administrative duties, the District is currently experiencing a backlog of permits that is, in some cases, delaying issuance up to 18 months.

LG&E is concerned that current backlogs in permitting will continue, and unfortunately, increase. This is an indirect cost Louisville Metro cannot afford. Such backlogs prevent the implementation of projects that reduce emissions, result in increased construction costs, and dissuade economic development by reducing the market responsiveness of businesses in Louisville Metro.

Before adding any new programmatic requirements, LG&E recommends that the Board evaluate (1) the District's current regulatory and administrative obligations and (2) the new regulatory and administrative obligations to be added by the proposed STAR Program to ensure that the District can meet its current obligations and successfully implement the proposed STAR Program

* * * * *

APPENDIX 1

Education

Ph.D., Toxicology, University of Texas at Austin, 1992

B.A., Psychology, University of Texas at Austin, 1984

Professional Registrations/Certifications

- Diplomate of the American Board of Toxicology
- Secretary, Central Texas Chapter Air & Waste Management Association
- National Member, Air & Waste Management Association
- TCEQ Protective Concentration Limit (PCL) Steering Subcommittee
- Member, Society of Toxicology

Experience

Senior Scientist, Signature Science, LLC, Austin, TX, March 2004-Present

Senior Scientist, ENSR Corporation, Austin, TX, January 2001 – February 2004

Senior Scientist, MFG Inc., Austin, TX, January 2000 – December 2000

Senior Scientist, URS Corporation, Austin, TX, August 1998- December 1999

Senior Toxicologist (Technical Specialist), Texas Natural Resource Conservation Commission, Austin, TX, December 1994 -August 1998

Staff Scientist, Radian Corporation, Austin, TX, January 1991-July 1994

Fields of Experience

Dr. Fraiser is a board certified toxicologist who specializes in human health risk assessment. She has approximately 16 years of experience in the areas of exposure and risk assessment, development of risk-based cleanup criteria, development of quantitative toxicity criteria, health effects and toxicology research, data collection strategies for risk assessment, litigation support, and risk communication. Particular strengths are in:

- Air toxics risk assessment;
- Toxicological evaluations;
- Exposure modeling;

- Development of innovative risk-based approaches;
- Communication of risk concepts;
- Agency negotiations; and
- Litigation support.

Dr. Fraiser is recognized both regionally and nationally in the area of human health risk assessment. She has been contracted in the past by a number of trade organizations to provide reviews and critiques of EPA risk assessment methodologies.

Litigation Support

- Provided critical testimony on potential risks associated with emissions from a commercial hazardous waste incinerator. The Kentucky Department of Environmental Protection attempted to revoke the facility's RCRA Interim Status RCRA Part B permit for alleged violations of RCRA and the Clean Air Act. As a result of the combined testimony of Dr. Fraiser and one of her colleagues, the client's request for a restraining order was granted, the facility remains open, and 75 employees kept their jobs.
- Developed expert opinion and provided testimony in a criminal case hearing regarding the potential for health effects associated with relatively short-term exposure to benzene concentrations above the Maximum Contaminant Level (MCL) in groundwater.
- Prepared to provide expert testimony on potential risks associated with lead and total petroleum hydrocarbon (TPH) levels detected in street sweepings for a criminal case hearing. Issues considered included potential risk associated with contaminant levels that were detected and potential for matrix interferences associated with laboratory methods. The case was ultimately settled before going to trial.
- Served as an expert witness on toxicology and risk assessment issues in a contested case hearing involving the Texas Natural Resource Conservation Commission (TNRCC) and the first Boiler & Industrial Furnace (BIF) to be permitted under Subpart H of 40 CFR 266 in the state of Texas (only second BIF to be permitted in the nation).

Power Plant Risk Assessments

- Conducted a risk evaluation of site operations that described potential impacts to on-site workers, the surrounding community, and ecological receptors. In combination with information on chemical hazards, local exposure patterns, and available local media

concentrations, toxic release inventory (TRI) data were used to identify chemical release and material handling practices at the plant that may warrant further study or action.

- Served as project manager and technical lead for multipathway exposure and risk assessments conducted for three lignite-fired utility plants. Toxic Release Inventory (TRI) data were used as the basis for emission estimates.
- Served as project manager and technical lead for mercury exposure and risk assessments conducted for three lignite-fired utility plants in which the Electric Power Research Institute's (EPRI's) Dynamic Mercury Cycling model was used. TRI data were used as the basis for emission estimates.

Toxicological Evaluations and Risk-Based Regulatory Criteria Development

- Developed an alternate to EPA's acute inhalation toxicity benchmark for nickel and nickel compounds on behalf of a commercial client based on site-specific speciation data and information from the toxicological literature.
- Used the National Library of Medicine's ChemIDPlus database to search for compounds with similar chemical structures to dye constituents and information on chemical structure to identify appropriate surrogate health benchmarks for dyestuffs lacking health benchmarks.
- Developed an Emergency Response Planning Guideline (ERPG) for a reactant (thionyl chloride) used in organic synthesis, which involved estimating toxicological properties of the previously uncharacterized compound on the basis of knowledge of chemistry concepts (i.e., stoichiometry of hydrolysis).
- Developed water quality criteria for methyl isobutyl ketone and methyl isobutyl carbinol that are protective of human health and domestic animals utilizing criteria set forth in the Illinois Environmental Protection Agency Water Quality Standards. Reviewed available toxicology data and recommended a suitable chemical for use as a surrogate in calculating aquatic criteria in the absence of toxicological data for methyl isobutyl carbinol.
- Performed a human health exposure and risk assessment for Rodeo® herbicide based on its intended use patterns, including applicator exposure, consumer safety, and terrestrial wildlife. The product subsequently received registration approval in the state of Connecticut.

- Reviewed toxicity data and derived an inhalation reference concentration (RfC) for cesium oxide, a gasoline additive that is used in France, using EPA's "Interim Methods for Development of Inhalation Reference Concentrations" on behalf of a commercial client.
- Served as primary author on a successful delisting petition for di-n-octylphthalate in which similarly-structured phthalates were evaluated.
- Reviewed toxicity studies from the chemical inventory of a large chemical company and made recommendations for submittal under TSCA 8E (Toxic Substances Control Act).

Risk Based Corrective Action

- Served as task leader for over 75 human health risk assessments and/or risk-based evaluations conducted in support of Resource Conservation Recovery Act (RCRA) closures or under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) for both commercial companies (petrochemical, agrochemical/pesticide, gas supply, aluminum, electric utility, cement kiln) and government clients (Army Corp of Engineers [USACE], Air Force Center for Environmental Excellence [AFCEE], Air Force Bases [Cannon, Davis-Monthan, Holloman, Langley, Maxwell]). Responsibilities included oversight and coordination of staff conducting modeling and reporting, representation of clients in Agency meetings, and complete responsibility for all financial and technical aspects of the risk assessments.
- Served as task leader for two human health risk assessments and one ecological risk assessment for an active petroleum depot in Southeast Asia. Responsibilities included oversight and coordination of both U.S. and Asian staff conducting sampling, modeling, and reporting for the project, representation of the client before a health panel of scientists convened to review the risk assessments, and complete responsibility for all financial and technical aspects of the risk assessment project. The risk assessment was conducted in a manner consistent with International guidance on the conduct of risk assessments. An extensive exposure pathway analysis was conducted for the site, including inhalation of vapors from indoor and outdoor air, dermal contact with soil and water, ingestion of soil and water, and uptake through the food chain (i.e., vegetables, chicken, and eggs).
- Developed numerous approaches to ensure internal consistency in risk assessments conducted by Texas Natural Resource Conservation Commission (TNRCC) personnel, the review of risk assessments submitted to the TNRCC, and data collection procedures while employed by the TNRCC. Dr. Fraiser also played a critical role in developing a risk-based corrective action rule package (Texas Risk Reduction Program) and technical support guidance documents for the proposed rule.

- Involved in a large-scale project in which risk-based tools for use by the Air Force were evaluated and recommended. Risk-based cleanup options at Installation Restoration Program (IRP) and Resource Conservation and Recovery Act (RCRA) sites located on Air Force Bases were reviewed to identify Records of Decision (RODs) amenable to modification.
- Participated in the development of an approach for establishing cleanup criteria for Air Force Bases nationwide as part of the Rational National Standards Initiative (RNSI). During the course of the project, Dr. Fraiser was involved in negotiations with military personnel and regulators.

Permitting Support

- Served as task leader for over two dozen human health risk assessments conducted in support of RCRA Part B permit applications for hazardous waste combustion units at chemical plants, waste management facilities, army depots, and cement kilns. Responsibilities included oversight and coordination of staff conducting modeling, and reporting for the project, representation of clients in Agency meetings, and complete responsibility for all financial and technical aspects of the risk assessments.
- Developed technical comments on EPA Risk Assessment Protocols for Hazardous Waste Combustion Facilities on behalf of the Louisiana Chemical Association (LCA) and the Cement Kiln Recycling Coalition (CKRC).
- Had primary responsibility within the Toxicology & Risk Assessment Section for implementation of the Texas Natural Resource Conservation Commission's (TNRCC) Combustion Strategy.
- Represented the TNRCC in an EPA work group to evaluate Maximum Achievable Control Technology (MACT) standards developed under the Clean Air Act for hazardous waste incinerators, cement kilns, and lightweight aggregate kilns. Highly advanced technical support documentation was critically reviewed and concerns and ideas regarding each standard were conveyed to EPA during the preproposal stage.
- Served as an external peer reviewer for a draft exposure and risk assessment guidance document developed by EPA Region 6 for conducting exposure and risk assessments at facilities that burn hazardous waste ("Protocol for Screening Level Human Health Risk Assessment at Hazardous Waste Combustion Facilities" and "Screening Level Ecological

Risk Assessment Protocol for Hazardous Waste Combustion Facilities”) while employed by the TNRCC.

Publications and Conference Proceedings

Dr. Fraiser has authored or co-authored numerous human health risk assessment papers and has been a major contributor to many technical reports in the area of human health risk assessment.

Fraiser, L.H., and Chaudhuri, I. Short-Term Toxicity Benchmark for Nickel Oxide. To be presented at the 42nd Annual Society of Toxicology Meeting. March 9 – 14, 2002. Salt Lake City, Utah.

Fraiser, L.H., and Ruffle, B. Chemical Regulations with Business Implications. Environmental Protection. June, 2002.

Fraiser, L.H., and Chaudhuri, I. Short-Term Toxicity Benchmark for Nickel Oxide. International Conference on Incineration & Thermal Treatment Technologies Proceedings. May 13 -17, 2002. New Orleans, Louisiana.

Fraiser, L.H., and Chaudhuri, I. Short-Term Toxicity Benchmark for Nickel Oxide. Proceedings of the Air & Waste Management Association. April 16 - 19, 2002. St. Louis, Missouri.

Fraiser, L.H., Chaudhuri, I, and Smith, D. EPA’s Dioxin Reassessment – Potential Impacts to the Regulated Community. Proceedings of the Air & Waste Management Association. June 24 - 28, 2001. Orlando, Florida.

Fraiser, L.H., Roeck, , D., and Smith, D. New Developments in Dioxin Regulation – Potential Impacts on the Regulated Community. International Conference on Incineration & Thermal Treatment Technologies Proceedings. May 14 -18, 2001. Philadelphia, Pennsylvania.

Fraiser, L.H.,oeck, , D., and Smith, D. Current Environment of Hazardous Waste Combustion. International Conference on Incineration & Thermal Treatment Technologies Proceedings. May 14 - 18, 2001. Philadelphia, Pennsylvania.

Fraiser, L.H., and Pope, P.G. 'Hazardous Waste Combustion Risk Assessment — Artifact or True Risk?' International Conference on Incineration & Thermal Treatment Technologies Proceedings. May 8-12, 2000. Portland, Oregon.

Fraiser, L.H., and Lewis, D. 'Detection Limits: Practical Implications for Risk Assessments Conducted on Hazardous Waste Combustion Units.' Presented before the Louisiana Chemical Association. September 9, 1999. Baton Rouge, Louisiana.

Fraiser, L.H., Tachovsky, J.A., King, M.L., McCoy, J.T., and Haws, L.C. 'Hazardous Waste Combustion Risk Assessment Experience in the State of Texas.' International Conference on

Incineration & Thermal Treatment Technologies Proceedings. pp. 189-196. May 11-15, 1998. Salt Lake City, Utah.

Fraiser, L., McCoy, J.T., Perry, C., King, M., and Haws, L.C. Screening Risk Analysis for the Bayer Corporation Facility in Baytown, Texas. TNRCC publication number AS-120, AS-120A, and AS-120B. November 1996.

Fraiser, L., Lund, L., Tyndall, K., King, M., Schultz, D., and Haws, L. 'Case Studies in Risk Assessment for Hazardous Waste Burning Cement Kilns in Waste Combustion' in Boilers and Industrial Furnaces Proceedings. pp.208-225. March 26-27, 1996. Kansas City, Missouri.

Fraiser, L., Lund, L., Hueske, K., and Haws, L.C. 'Indirect Risk Assessment: Case Studies of Hazardous Waste Combustors'. Toxicologist 30:6, 1996.

Fraiser, L., Lund, L., Hueske, K., King, M., and Haws, L.C. Screening Risk Analysis for the North Texas Cement Company (NTCC) Facility in Midlothian, Texas. TNRCC publication number AS-71, AS-71A, and AS-71B. January 31, 1996.

Fraiser, L., Lund, L., Hueske, K., King, M., and Haws, L.C. Screening Risk Analysis for the Texas Industries (TXI) Facility in Midlothian, Texas. TNRCC publication number AS-72, AS-72A, and AS-72B. November 2, 1995.

Ramu, K., Fraiser, L., Mamiya, B., Ahmed, T., and Kehrer, J.P. 'Acrolein Mercapturates: Synthesis, Characterization, and Assessment of Their Role in the Bladder Toxicity of Cyclophosphamide.' Chem. Res. Toxicol. 8:515-524, 1995.

Fraiser, L., and Kehrer, J.P. 'Effect of Indomethacin, Aspirin, Nordihydroguaiuretic Acid, and Piperonyl Butoxide on Cyclophosphamide-Induced Bladder Damage.' Drug Chem. Toxicol. 16(2):117-133, 1993.

Fraiser, L., Barnett, J.W., and Hixson, E.J. 'Toxicity Equivalents for Chlorinated Hydrocarbon Pesticides Lacking EPA-Verified Toxicity Values.' Toxicologist 14: 1540, 1994.

Kanekal, S., Fraiser, L., and Kehrer, J.P. 'Pharmacokinetics, Metabolism, and Lung Toxicity of Cyclophosphamide in C57/Bl6 and ICR Mice.' Toxicol. Appl. Pharmacol. 114:1-8, 1992.

Fraiser, L., and Kehrer, J.P. 'Murine Strain Differences in Bladder Toxicity of Cyclophosphamide.' Toxicol. 75:257-272, 1992.

Fraiser, L., Kanekal, S., and Kehrer, J.P. 'Cyclophosphamide Toxicity: Characterizing and Avoiding the Problem.' Drugs. 42(5):781 -795, 1991.

APPENDIX 2



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Igor B. Shnayder

Summary

Igor has conducted air quality related projects and has been involved in numerous projects with air quality modeling. Currently, he is involved in emissions inventory and air permitting projects, including Title V and PSD Permits. Igor is knowledgeable in state and federal environmental regulations for different industries and has substantial experience in word processing, spreadsheet and CAD applications.

Prior to his career in environmental consulting, Igor was a meteorological service shift supervisor and weather forecaster of Sheremetjevo International Airport in Moscow, Russia for over four years. He directly interacted with both ground and air dispatchers of the airport. He also attended weekly briefings of the airport management.

Key Expertise

Education

M.S. Meteorology and
Climatology, Moscow
State University,
Moscow, Russia, 1979

Professional Affiliations

Air and Waste
Management
Association

American Foundrymen's
Society

- Ambient Air Quality Modeling
- AutoCAD
- Construction and Operating Permits
- PSD Reviews and Permits
- Emission Inventories
- Risk Management Plans
- SPCC and ICP Plans
- Environmental Regulatory Audits
- SARA 312 and 313 Reporting
- Pollution Discharge Elimination System Permits and Storm Water Pollution Prevention Plans

Project Experience

Training

AutoCAD Drawings; Carter & Burgess, Fort Worth, Texas, 1994

Air and Waste Management Association Workshops and Seminars, 1995 – 1999

Texas Title V and Air Permitting Seminars, 1996 – 1998

American Foundrymen's Society Texas Chapter Seminars, 1997 – 1999

EPA's SARA 313 Reporting Workshop, 1999

AFS Foundry Environmental Seminar 101 - 2000

Ambient Air Quality Modeling

Conducted extensive ambient air quality modeling using U.S. EPA approved SCREEN3 and ISC3 models. These models have been used for effects evaluation and evaluation of compliance with the state standards. Used PCRAMMET to prepare or modify meteorological files for consecutive use in the modeling. Used ISCST3 model to conduct over a dozen NSR projects and four State and NAAQS PSD projects for foundries and chemical and petrochemical facilities. Used both ISC and ISC-PRIME versions of the model as necessary. Mastered a Windows-based version of the ISC3/ISC3-PRIME.

Mastered the use of SLAB, DEGADIS, and TSCREEN for extensive event consequences assessment and risk assessment projects for two chemical and petrochemical facilities. Familiar with several other refined dispersion models used in hazardous/toxic air pollution releases modeling.

Construction and Operating Permits

Prepared new source construction and operating permits for facilities in Arkansas, Illinois, Kansas, Oklahoma, and Texas. Industries included synthetic organic chemical manufacturing, pulp and paper, natural gas processing, foundries, and other. Developed emission factors; performed potential-to-emit calculations; prepared regulatory requirements analyses, CAD drawings, and application forms for permit applications; and performed computer modeling of emissions.

Title V General Operating Permits

Prepared general operating permit applications for more than five companies in Oklahoma and Texas. Facilities covered included compressor stations and gas processing plants. Performed emission calculations using the most recent emission factors and computer models, conducted regulatory analysis, and prepared application reports. Demonstration of compliance with the existing requirements included an SO₂ ambient air concentration using EPA ISCST3 computer model.

Title V Full Operating Permits

Prepared standard operating permit applications for companies in Arkansas, Kansas, Louisiana, Missouri, Oklahoma and Texas. Permit applications were prepared for iron and steel foundries, synthetic organic chemicals manufacturing units, sulfur recovery units, cryogenic units, a brick manufacturing facility, and a polypropylene plant. The scopes of work included emission units identification; selection of significant emission units;



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development of emission factors, potential-to-emit calculations, and regulatory analysis; permitting strategy development; and preparation and submittal of necessary forms and documents.

Historical PSD Reviews and PSD Permits

Was actively involved in preparation of PSD reviews and permits for pulp and paper, secondary metal production, petroleum refineries, and car manufacturing facilities. Scopes of work included analysis of authorizations for expenditures to separate modifications, evaluation of PSD applicability for each modification, emissions calculations, and netting procedures for the modification projects. In two cases, PSD permit preparation required extensive ambient air computer modeling followed by refined modeling to demonstrate to the state authorities that the projects can meet applicable requirements.

Permit Amendments and Minor Permit Modifications

Minor permit modification procedures were used in cases when state regulations allow for simplified permitting procedures for new facilities construction or modification. Preparation of such applications usually required process description, process flow diagrams and plot plans, emission calculations, demonstration that the project meets requirements for simplified permitting process, and completion of appropriate forms.

Emissions Inventories

Emissions Inventories were prepared both as separate documents and as a part of Title V permit applications as required. Identified emission units, developed emission factors, and calculated emissions for ferrous and non-ferrous foundries, pulp and paper mills, SO2MI facilities, gas stations and plants, petrochemical facilities, and other. Developed computerized spreadsheets to simplify calculations for most common emission units such as gas combustion sources, paint booths, cooling towers, etc. Used TANKS3, GRI-GLYCalc, and other computer models as necessary.

Risk Management Plans (RMP)

Prepared Risk Management Plans for an organic chemical manufacturing facility and for gas processing and expandable polystyrene manufacturing facilities. The scope included an identification of the RMP chemicals, extensive dispersion modeling to estimate the worst-case and alternative release scenario end-point distances, development of Program 2 and 3 Prevention programs, and preparation of the submittal documents.



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SPCC and ICP Plans

Reviewed and updated several Spill Prevention Control and Countermeasure (SPCC) plans and converted two of them into the Integrated Contingency Plan (ICP) format. Those plans were prepared for iron foundries.

Air Monitoring Programs

Developed and reviewed ambient air monitoring programs for two landfills to include applicable requirements and to develop a monitoring strategy for VOC compounds in accordance with the Michigan Department of Natural Resources (MDNR) documents.

SARA 312 and 313 Reporting

Prepared 1997 – 2000 Tier II and Form R and A reports for ferrous and non-ferrous foundries in Minnesota, Pennsylvania, Texas and other states. Analyzed MSDS for steel and iron foundry chemicals and developed a list of chemicals subject to SARA 313 reporting based on the actual usage. Calculated the reported chemical releases for each SARA stream and completed the required forms using EPA software.

MACT Long Form Questionnaire

Prepared MACT Long Form Questionnaire responses for two foundries.

Standard Exemptions/Permits by Rule

Prepared Texas Natural Resource Conservation Commission (TNRCC) Standard Exemptions and Texas Commission for Environmental Quality (TCEQ) permit by rule (PBR) registrations for many different companies. Source types include internal combustion engines, tanks and loading operations, surface coating operations, and a variety of others.

Environmental Regulatory Audits

Conducted and participated in complex environmental regulatory audits of eight foundries. Scope of work for each facility included reviews of emergency and contingency plans (including SPCC Plans); air, water, stormwater, and solid waste disposal permits; hazardous and non-hazardous waste management systems; SARA 312 and 313 reports, and other.



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Randy D. Parmley, P.E.

Vice President

Summary

Randy has 23 years experience in air quality consulting. Although his experience encompasses almost every aspect of air quality, his primary areas of expertise are in the areas of permitting and atmospheric dispersion modeling. Randy has worked extensively with the refining and petrochemical industries and has a strong reputation preparing and negotiating large and complex flexible, PSD, and Title V permitting Projects.

Randy has prepared well over 100 air permit applications and over 200 supporting dispersion modeling analyses. He has conducted regulatory, permitting, and modeling seminars in North America, South America, Europe and Asia. He has also served as a dispersion modeling expert witness on numerous occasions. Randy's expert witness experience includes contested permit hearing, disaster/event modeling evaluations and testimony, and a variety of health-effect related toxic tort support efforts.

Randy's experience in emissions inventory preparation, NOx SIP evaluations, air regulatory compliance assessments, toxic risk evaluations, control strategy applications, monitoring and sampling programs, and a variety of air-related and interdisciplinary environmental consulting applications complete his professional profile.

Randy currently serves as the Houston Client Service Manager. In this role, he is responsible for developing and managing a group of dedicated air quality consultants serving client needs both in the Houston office and at client facilities. Randy has previously served as both a first and second line manager with direct supervision of up to 38 engineers and scientist.

Education

B.S. Environmental
Engineering, University
of Texas, Austin 1979

B.S.
Natural Science/
Chemistry, 1976

License/ Registration

State of Texas Professional
Engineers License No.
75280

Key Expertise

- Air Permitting
- Emissions Inventory and Dispersion Modeling
- Air Control Strategy Applications
- Air Monitoring and Sampling



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Experience

Professional Societies

Awardee U.S. EPA
Pollution Fellowship,
1978-1979
Air and Waste Management
Association

- V.P, Houston Client Service Manager, Sage Environmental Consulting, August, 2001
- Manager, On-Site Business Services, URS Corporation Houston, 1999-2001
- Principle Engineer, URS Corporation, 1998 - 2001
- Senior Consultant, McCulley, Frick, and Gilman, April, 1998 - September, 1998
- Senior Staff Project Director, Radian Corporation, 1994-April, 1998.
- Section Head, Air Regulatory Analysis, Radian Corporation, 1993-1994.
- Group Leader, Atmospheric Sciences, Radian Corporation, 1991-1993.
- Senior Engineer, Radian Corporation, 1989-1994.
- Consultant/Environmental Engineer, Austin, TX, 1984-1988.
- Staff Engineer, Radian Corporation, Austin, TX, 1983.
- Environmental Engineer, Radian Corporation, 1981-1982.
- Environmental Engineer, U.S. EPA, Region 6, 1980-1981.
- Environmental Engineer, LACE Engineering, Austin, TX, 1979.
- Environmental Engineer, University of Texas Center for Energy Studies, 1978.

Project Experience

Air Permitting, Emission Inventory, and Modeling

Randy's recent technical responsibilities include preparing, negotiating, implementing and providing compliance support for all existing permits and pending permits for a large Gulf Coast refinery. Randy has served as principal in-house consultant for large capital projects involving refinery coker units, low sulfur motor gasoline units, sulfur conversion units, development and implementation of complex bubble concept permitting, and Title V permitting. Randy's responsibilities during this assignment included working closely with refinery economic planners and field operation managers as well as with environmental staff. Through this multi-year effort,



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Randy gained a detailed and working knowledge of refinery operations and applicable regulations affecting refinery operations.

Randy has successfully acquired numerous air permits and permit exemptions in the refining, synthetic organic chemical, cement, pharmaceutical, metallurgical, pulp and paper, mineral, natural gas, plastics, rubber, surface coating, surface mining, hazardous waste incineration, industrial gases, Department of Defense, and electric power industries.

Randy served as Project Director of the largest permitting project in EPA Region 6 history, the multibillion-dollar expansion of a complex plastics manufacturing complex on the Gulf Coast. The project included extensive dispersion modeling and BACT analyses. For this client, Randy also served as project manager for conducting the only point-source ozone modeling effort completed in Texas.

Randy has extensive experience in data development and prerequisite information to run EPA-approved atmospheric dispersion models. Randy is proficient with Industrial Source Complex models, various Episodic and Climatological models, and several disaster models. Randy has served as Project Director on numerous special studies modeling projects ranging from model comparisons projects to radioactive disaster modeling.

Randy has served as an expert witness in dispersion modeling for contested permit hearings, event simulations, toxic risk evaluations, and a variety of toxic tort cases. His engineering and modeling background enable Randy to evaluate and communicate complex emission release and modeling concepts in an understandable and credible manner. As a result he has been used by such firms as Fulbright & Jaworski, Baker -Botts, Jones-Day, Benchenstein & Oxford, Rodriquez, Colvin & Chaney and numerous other firms for expert witness support.

Randy has used his modeling experience and biological background to perform toxic risk assessment for the refining, synthetic organic chemical metallurgical, pharmaceutical, and refining industries for both regulatory and legal purposes.

Randy has served as Project Director for several international modeling application projects involving neural net technology for predicting next day ozone pollution episodes.

Randy has served as Project Director and key modeling contact on several Department of Energy RCRA permit projects involving open burning/open detonation activities.

Randy served as Project Director for a Clean Air Act Amendment Title V permitting effort for one of the largest refineries in the United States. For this effort, Randy utilized his Title V expertise to direct the permit strategy, emission inventory development, air audit, compliance demonstration, and permit application tasks for this extensive permitting project. Randy has also completed other Title V strategy manual projects addressing site-specific considerations for SOCOMI and refining clients.



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Randy has directed numerous Title V permit applications for various petroleum marketing and pipeline clients.

Air Control Strategy Applications

Randy served as a key engineer in the development of a streamlined permitting approach for selective catalytic reduction technology as part of a joint refinery/TNRCC task force. Randy's extensive knowledge of air pollution abatement technology and engineering principles to evaluate air pollution controls strategies for Lowest Achievable Emission Rate (LAER), Best Available Control Technology (BACT) and Reasonably Available Control Technology (RACT) was utilized in developing this permitting approach.

Randy has previously served as an EPA Region 6 Control Technology Specialist for State Implementation Plan applications. He worked extensively with Flue Gas Desulfurization (FGD) technologies in the 1980's. In this capacity, he published technology reviews for both United States and Japanese FGD Processes.

Air Monitoring and Sampling

Randy was instrumental in establishing and managing local and regional ambient air monitoring networks for Radian Corporation. He designed the air monitoring network in Monterrey, Mexico and Alba Iulia, Romania. He served as data editor and coordinator for Houston Regional Monitoring (HRM) and PSD monitoring Networks. Randy prepared Radian's in-house PSD Ambient Air Monitoring Operator's Manual.

Randy was the Project Director for several efforts to define and establish continuous emission monitoring and reporting requirements for industrial sources in Thailand and Chile.

Randy gained extensive source sampling instrumentation and field experience while serving as a sampling field chief for a manufacturer of source testing equipment.



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Publications/Presentations

Parmley, R.D., I. Shnyder, and S. Dillard, "Strategies for Modeling Facility Maintenance Emissions," presented at the National Air and Waste Management Association Conference, June 2004

Parmley, R.D., "An Evaluation of the Flexible Permit/PAL Program in Texas", Presented at the National Petrochemicals and Refiners Association Annual Environmental Conference in New Orleans, Louisiana, April 2003.

Parmley, R. D. "Recommendations for a Continuous and Parametric Monitoring and Reporting Program for Chile", May 1998.

Parmley, R.D., T.DeFries, "Development of a Neural Net Model to Predict Next Day Ozone Concentrations in Bangkok, Thailand." Presented at the Pollution Control '97 International Conference in Bangkok, Thailand.

Parmley, R.D., G.Baker, "Feasibility Study for the Modernization of the Air Quality Monitoring Network in Venezuela", Presented at the Pollution Control '97 International Conference in Bangkok, Thailand.

Parmley, R. D. "Recommendations for an Industrial Monitoring and Reporting Program to Comply with Section 80 of the National Environmental Quality Act", March 1996.

Parmley, R.D., D. Schmitt, "Calculation Methodologies for Refinery Flexible Permit Applications", June 1995.

Parmley, R.D., S.A. Smith, "Comparison of ISC and HEM Modeling Approaches and Evaluation of Other Toxic Risk Uncertainties", Radian Corporation, presented at the National Air and Waste Management Association Conference, 1992.

Hunt, M. and R.D. Parmley, "Predicting Ozone Concentrations with RPMIIS," Radian Corporation, presented at the National Air and Waste Management Association Conference, 1991.

Parmley, R.D., Site-Specific Evaluation of Potential Cancer Risk Associated with Ethylene Oxide Emissions from the Texaco Chemical, Port Neches Facility. Radian Corporation, December 1990.

Smith, S. and R.D. Parmley, Site-Specific Evaluation of Potential Cancer Risk Associated with 1,3-Butadiene Emissions from the Texaco Chemical, Port Neches Facility, Radian Corporation, April 1990.

Parmley, R.D., Handbook of Chemical Analyses for FGD Operators. Prepared for the Electric Power Research Institute, San Jose, CA, 1983.

Gates, N. and R.D. Parmley, "NO_x and SO_x Flue Gas Removal Technologies in Japan," Radian Corporation, Austin, TX, 1982.

Parmley, R.D., Radian's PSD Operating Manual. Austin, TX, 1982.



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Parmley, R.D. and P. Murin, "Characterization of VOC Emission Sources and Potentially Applicable Emission Control Technologies," Radian Corporation, Austin, TX, 1981.

Parmley, R.D., "Cost of Controlling Previously Uncontrolled Sources of VOC Emissions in Harris County," Radian Corporation, Austin, TX, 1981.

Parmley, R.D. and H.R. Parish, "Resource Recovery Cost for the Electric Power Industry," presented at the Electric Power Industry Conference and at the American Chemical Society Conference, 1980.

Parmley, R.D. and H.R. Parish, "Present Status of Development of Flue Gas Desulfurization in the United States," Center for Energy Studies Press, 280 pages, 1979.

APPENDIX 3